FALL/WINTER 1997

TRIALS SEARCH GUIDE

HIV Clinical Trials in California

Compiled by the Community Consortium

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Introduction

Clinical trials are often the first place people with HIV can gain access to promising new medical treatments. They are an important option for anyone with HIV. Unfortunately, learning about clinical trials can be difficult and confusing. That's where *Trials Search* and this *Guide* can help.

Trials Search is a database of open HIV clinical trials in the United States. *Trials Search* matches clinical trial entry requirements with an individual's medical history and current health status and produces a personalized list of studies for which he or she might qualify. *Trials Search* is a free service. Call (800) 492-5777 for more information or to receive a questionnaire.

The *Guide* includes information about all clinical trials of which we are aware that are currently enrolling patients in California. No endorsement is made of any trial described herein. Every reasonable effort has been made to ensure that the information presented in the *Guide* is accurate, comprehensive and up-to-date. However, eligibility and other criteria are subject to change, and trials may close to patient enrollment at any time.

The Community Consortium welcomes information about all clinical trials available throughout the United States for inclusion in *Trials Search*. Any trial which has been reviewed and approved by an Institutional Review Board may be included. Institutional Review Boards are committees which are set up to review research involving human subjects to ensure that studies are ethical and scientifically sound. Anyone with information appropriate for publication is asked to call the Consortium at (415) 476-5777 or (800) 492-5777.

Trials Search and the database HIV Clinical Trials in the United States are also available on the Internet at:

http://hivinsite.ucsf.edu/tsearch

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• Research staff at more than 60 trial sites who furnished the bulk of the information contained in the Guide. This project would not have been possible without their considerable expertise and generous contribution of time and energy.

The following publications for their reliability and usefulness:

• *AIDS/HIV Treatment Directory* published by the American Foundation for AIDS Research (AmFAR).
• *Bulletin of Experimental Treatments for AIDS (BETA),* from the San Francisco AIDS Foundation.
• *Treatment Issues* from the Gay Men's Health Crisis (GMHC) for the Glossary of Medical Terms which is a reference and basis for some of our glossary entries. The online Guide uses the GMHC Glossary as a whole.

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Trials search guide.

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An Association of Bay Area
HIV Health Care Providers

The Community Consortium is affiliated with the
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Table of Contents

i Introduction

1 How to use this Guide

3 Trial Finder: quick list of trials

9 HIV Clinical Trials in California

91 Compassionate Use, Expanded Access and Treatment IND Programs

93 California AIDS Drug Assistance Program (ADAP)

97 Pharmaceutical Company Sponsored Patient Assistance Programs

101 Common Questions about Clinical Trials

105 How to Enroll in a Clinical Trial

107 Women and Clinical Trials

109 Children and Clinical Trials

111 Youth and Clinical Trials

113 Injection Drug Users and Clinical Trials

115 List of Clinical Trials Sites

119 Community Consortium Sites and Providers

121 Resources

127 Glossary

133 Index

How to use this Guide

The *Trials Search Guide* is written for people who are living with HIV disease and for their health care providers. It should be used as one resource among many in learning about HIV disease. The *Guide* will probably be most useful to people who already know something about their own health and about HIV. If you think you need to learn more, talk to your health care provider and contact some of the Resources beginning on page 121.

Understandable language

One of the stumbling blocks for many people in learning about HIV and clinical trials is confusing "medical jargon". We have tried to avoid using technical language whenever possible, but sometimes there is no simple way to describe technical information. If you come across a word or idea that you don't understand, you can check the Glossary on page 127. It may be helpful to discuss any remaining questions with your health care provider, or the contact person listed for the clinical trial. More information is also available from one or more of the Resources listed on page 121.

Other programs for treatment access

Gaining access to treatments can be complicated and confusing. If a medication you are seeking is not being studied in a clinical trial in your area, check page 91 for a listing of Expanded Access, Compassionate Use and Treatment IND Programs. If the treatment has been approved for sale, but you need help to pay for it, check the list of AIDS Drug Assistance Covered Drugs and pharmaceutical company sponsored Patient Assistance programs on pages 93 - 99.

Questions about clinical trials, and issues for special groups

To answer some important questions about clinical trials, and about who can join a clinical trial, we have included sections on common questions about clinical trials, how to join a clinical trial, and issues about clinical trials for women, children, youth and people who use injection drugs. These sections are found on pages 101 through 113.

Trial Finder and Trial Descriptions

The 168 trials listed in the *Guide* are arranged by the disease or condition being studied, or by the group of people for whom the study is intended. Trial Finder on pages 3 - 8 is a quick reference for trials in which you may be interested.

If you are interested in a certain drug or treatment for a particular disease, you can also look it up in the Index, starting on page 133. The Index will tell you which page to turn to in the *Guide*.

How to use this Guide

For each clinical trial, we include the following information:

Title: This is the official name of the trial. Most trials also have letters or numbers given before the title. This is the protocol number. For example, ACTG 276 means this is AIDS Clinical Trials Group study number 276.

Type of Treatment: This lists the type or "class" of drugs being tested in the study. The different types of anti-HIV drugs attack the virus in different ways. Older anti-HIV drugs such as AZT (also called 2DV), ddI, ddC and d4T are all a type of drug called a "nucleoside analog". Some newer drugs are called "protease inhibitors" and "non-nucleoside reverse transcriptase inhibitors".

Purpose: This is what the researchers are trying to learn from the trial. Below are a few of the most common reasons why studies are done.

- To learn if a drug is safe for people to take.
- To learn if a drug works.
- To compare two or more drugs.
- To compare two or more doses of the same drug.

About the study: This section describes what will happen during a trial, from the patient's perspective. We tell you how long the trial lasts, if you will know what drugs you are taking, how the drug is given (for example, pill, liquid or injection), if there are an unusual number of required visits to the clinic, or if you need to stay in the hospital.

Required: These are the entry requirements that you must meet before you can join the study. These are sometimes called "inclusion criteria." We have space to list only a few of the most important entry requirements. In many cases, there will be others.

Not allowed: You cannot join the study if you fit any of these criteria. These are sometimes called "exclusion criteria." Again, only the most important exclusion criteria are included. You may not be able to join this particular study because there is a good chance that you would be harmed by the study drug. Researchers examine your medical history and your laboratory tests to make sure you are not at "high risk" for experiencing harmful side effects. Many clinical trials require that your laboratory tests be "within normal limits," or at least in a safe range. This is to make sure you don't already have a medical problem that might become worse if you take the drug.

Women who are pregnant or breastfeeding may also not be able to join a clinical trial. This is because it is not known if taking the drug will harm the baby. Usually, women who have sex with men, and men who have sex with women, must agree to use birth control while they are in the study.

Location: This is where you need to go to participate in the study (the study "site"). We also give you the name of the person to call if you are interested. In most cases, you don't have to be a patient at the hospital or clinic where the study is located in order to join the study. For some studies, your doctor must contact the site first.

Trial Finder

	#	Condition	Medications	Page
New	1	HIV Infection	CSF Viral Load	9
New	2	HIV Infection	Genotypic Antiretroviral Resistance	9
New	3	HIV Infection	Fortovase, Ritonavir, Delavirdine, DMP-266, Adefovir	10
New	4	HIV Infection	SCH 52000 (Interleukin 10)	10
New	5	HIV Infection	PMPA	11
New	6	HIV Infection	Indinavir, 3TC, Delavirdine, AZT, d4T	11
New	7	HIV Infection	ddI, d4T	12
New	8	HIV Infection	SCH 52000 (Interleukin 10)	12
New	9	HIV Infection	Delavirdine, Nelfinavir, ddI, d4T	13
New	10	HIV Infection	Delavirdine, Indinavir, AZT, 3TC	14
New	11	HIV Infection	141W94, AZT, 3TC, Indinavir, Nevirapine, d4T	14
New	12	HIV Infection	1592U89, Indinavir, AZT, 3TC	15
New	13	HIV Infection	S-1153	15
New	14	HIV Infection	Indinavir, DMP-266	16
New	15	HIV Infection	141W94, Indinavir	16
New	16	HIV Infection	Indinavir, AZT, 3TC	17
New	17	HIV Infection	CD4-zeta Gene Therapy	17
New	18	HIV Infection	Cyclosporin	18
New	19	HIV Infection	XQ-9302 (Chinese Herbs)	18
New	20	HIV Infection	Nelfinavir, Hydrozyurea, d4T, ddI	18
New	21	HIV Infection	Nelfinavir (Viracept), AZT, 3TC	19
New	22	HIV Infection	d4T, ddI, Nelfinavir, Hydroxyurea	19
New	23	HIV Infection	1592U89	20
New	24	HIV and CMV Infection	Viral Load	20
	25	HIV Infection	Hydroxyurea, ddI, d4T	20
	26	HIV Infection	Hydroxyurea, ddI	21
	27	HIV Infection	Interleukin-12	21
	28	HIV Infection	GM-CSF	22
	29	HIV Infection	Interleukin-2	23
	30	HIV Infection	Leukocyte Interleukin	23
	31	HIV Infection in Men	Nandrolone Decanoate, Exercise	24
	32	HIV Infection	DMP-266, Indinavir, AZT, 3TC	24
	33	HIV Infection	Indinavir, AZT, 3TC	25
	34	HIV Infection	Remune, Indinavir, AZT, 3TC	25
	35	HIV Infection in Men	141W94, Invirase, Nelfinavir, Indinavir	26
	36	HIV Infection	Lobucavir	26

#	Condition	Medications	Page
37	HIV Infection	Indinavir, ddI, d4T	27
38	HIV Infection	141W94, AZT, 3TC	27
39	HIV Infection	CD4-zeta Gene Therapy, Interleukin-2	28
40	HIV Infection	CI-1012	28
41	HIV Infection	1592U89, Indinavir, DMP-266	29
42	HIV Infection	HIV-IT	29
43	HIV Infection	Nevirapine, Nelfinavir, d4T	30
44	HIV Infection	Adefovir Dipivoxil, Nelfinavir, Saquinavir, AZT, 3TC, d4T	30
45	HIV Infection	1592U89, AZT, 3TC	31
46	HIV Infection	AZT, 3TC, AZT/3TC, Protease Inhibitor	32
47	HIV Infection	DMP-266, Indinavir	32
48	HIV Infection	Adefovir Dipivoxil, Indinavir, AZT, 3TC, d4T	33
49	HIV Infection	G-CSF (Filgrastim)	33
50	HIV Infection	Viracept, AZT, 3TC	34
51	HIV Infection	rgp 160 Vaccine	34
52	HIV Infection	Fortovase, Nelfinavir	35
53	HIV Infection	Fortovase, Nelfinavir (2)	35
54	HIV Infection	Fortovase, Nelfinavir, Ritonavir	36
55	HIV Infection	bis-POM PMEA	37
56	HIV Infection	Nelfinavir, Ritonavir	37
57	HIV Infection	Stress Management	38
58	HIV Infection	Viral Load Observational study	38
59	HIV-Associated Anemia	Marrow Plus	39
60	Aphthous Ulcer Treatment	Thalidomide	39
61	Bacterial Infection Treatment	ABCD, Fungizone	40
62	Cervical Dysplasia Prevention	Isotretinoin	40
63	Cervical Dysplasia Treatment	DFMO	40
64	Oral/Esophageal Candidiasis Treatment	Itraconazole	41
65	Oral/Esophageal Candidiasis Treatment	Amphotericin B Colloidal Dispersion	41
66	Oropharyngeal Candidiasis Treatment	Fluconazole	42

	#	Condition	Medications	Page
	67	Oral/Esophageal Candidiasis Treatment	MK-0991, Amphotericin B	42
	68	Oropharyngeal Candidiasis Treatment	SCH 56592	43
	69	CMV Infection	1263W94	43
	70	CMV Retinitis Treatment	ISIS 2922	44
	71	CMV Retinitis Treatment	ISIS 2922, Ganciclovir	44
	72	CMV Retinitis Treatment	ISIS 2922	45
	73	CMV Retinitis Treatment	ISIS 2922	45
	74	CMV Retinitis Treatment	VIRACEPT (nelfinavir), Ganciclovir	46
	75	CMV Retinitis Treatment	Intraocular Cidofovir	46
	76	CMV Retinitis Treatment	RS-79070, IV Ganciclovir	47
	74	CMV Retinitis Treatment	GEM 132	47
	78	CMV Retinitis Treatment	Cidofovir, Ganciclovir	48
	79	CMV Retinitis Treatment	Ganciclovir, G-CSF	48
	80	Cryptococcal Meningitis Treatment	Fluconazole, Liposomal Amphotericin B	49
	81	AIDS Dementia Treatment	1592U89	49
	82	AIDS Dementia Treatment	Memantine	50
New	83	AIDS Dementia Treatment	1592U89	50
	84	Diarrhea Treatment	Octreotide	51
	85	Diarrhea Treatment	Questran, ADEK	51
	86	Diarrhea Treatment	Chinese Herbs	52
	87	Cryptosporidiosis Treatment	Nitazoxanide	52
	88	HIV-Related Upper GI Symptoms	Metoclopramide	53
New	89	Chronic Hepatitis Treatment	Lobucavir	53
	90	Histoplasmosis Treatment	AmBisome, Amphotericin B	54
	91	Herpes Simplex Treatment	Virend 15%, Acyclovir	54
	92	Herpes Simplex	Observational study	55
	93	KS Treatment	Tin Ethyl Etiopurpurin	55

	#	Condition	Medications	Page
	94	KS Treatment	Topotecan	55
	95	KS Treatment	Liarozole	56
	96	KS Treatment	Paclitaxel	56
	97	KS Treatment	LGD1069 (Targretin)	56
	98	KS Treatment	IM-862	57
	99	KS Treatment	Radiation	57
	100	KS Treatment	TNF Receptors	58
	101	KS Treatment	Piritrexim	58
	102	KS Treatment	Alpha Interferon, Ritonavir, d4T	58
	103	KS Treatment	Amifostine,Taxol	59
	104	KS Treatment	Viracept (Nelfinavir)	59
	105	KS Treatment	Piritrexim (2)	60
	106	KS Treatment	ALRT1057 Oral Capsules (2)	60
	107	KS Treatment	Toremifine	61
New	108	KS Treatment	9-aminocamptothecin (9-AC/DMA)	61
	109	KS Observational	Observational study	62
	110	Non-Hodgkin's Lymphoma Treatment	Gallium Nitrate	62
	111	AIDS-Related Lymphoma Treatment	Chemotherapy	63
	112	Non-Hodgkin's Lymphoma Treatment	Mitoguazone (MGBG), CHOP Chemotherapy	63
	113	Non-Hodgkin's Lymphoma Treatment	PEG L-Asparaginase	63
	114	Non-Hodgkin's Lymphoma Treatment	DaunoXome	64
	115	Epstein Barr-Associated Malignancies	5-Azacytidine	64
	116	AIDS-Associated Lymphoma Treatment	90Y-Lym-1	65
	117	Non-Hodgkin's Lymphoma Treatment	CHOP, d4T, 3TC, Indinavir.	65
	118	Non-Hodgkin's Lymphoma Treatment	Interleukin-2	66
New	119	Non-Hodgkin's Lymphoma Treatment	Topotecan	66
New	120	Non-Hodgkin's Lymphoma Treatment	Diethylhomospermine	67
New	121	MAC Prevention	Azithromycin	67
	122	MAC Treatment	Clarithromycin, Rifabutin, Ethambutol	68
New	123	Molluscum Contagiosum Treatment	Cidofovir Gel	68

#	Condition	Medications	Page
124	Prurigo Nodularis	Thalidomide	68
125	TB Treatment	Rifapentine, Isoniazid, Rifampin	69
126	TB Treatment	Rifampin, INH, Ethambutol, Pyrazinamide	69
127	Nutrition in HIV Infection	Peptamen, NuBasics, Vitamins	70
128	HIV Wasting Treatment	Nandrolone Decanoate	70
129	HIV Wasting Treatment	Testosterone, Exercise	70
130	HIV Wasting Treatment in Men	Oxandrolone	71
131	HIV Wasting Treatment	Megace, Testosterone	71
132	HIV Wasting Treatment	Serostim	72
133	HIV Wasting Treatment	Thalidomide	73
134	HIV Weight Loss in Women	Nandrolone Decanoate	73
135	HIV Wasting Treatment in Women	Oxandrolone	74
136	HIV Weight Loss	Observational study	74
137	HIV Wasting Syndrome	Observational study	74
138	Nutrition in Women with HIV	Observational study	75
139	Human Herpes Virus 8 Project	Developmental study	75
140	HIV Transmission	Educational Intervention	75
141	HIV Infection and the Central Nervous System	Observational study	76
New 142	Pharmacokinetics	CPI-1189 (Lu 02-584)	76
143	Pharmacokinetics	INH	76
144	Pharmacokinetics	SCH 56592.	77
New 145	Pharmacokinetics	Indinavir, Rifabutin	77

Studies for Pregnant Women, Newborns, Infants and Children

146	Mother-Newborn Transmission Prevention	Nevirapine	78
147	HIV Infection in Women	VIRACEPT, Invirase, 3TC, d4T	78
148	HIV Infection in Pregnant Women	ddI	79
New 149	HIV Infection in Pregnant Women	Indinavir, AZT, 3TC	79
New 150	HIV Infection in Pregnant Women and Infants	Nelfinavir, AZT, 3TC	80

	#	Condition	Medications	Page
	151	HIV Infection in Women in Labor	AZT	80
	152	HIV Exposure in Premature Infants	AZT	81
	153	HIV Infection in Newborns	1592U89, AZT	81
	154	HIV Infection in Infants and Children	AZT, 3TC, Nevirapine, 1592U89	82
New	155	HIV Infection in Infants	ALVAC HIV Vaccine	82
	156	HIV Infection in Children	bis-POM PMEA	83
	157	HIV Infection in Children	Interleukin-2	83
	158	HIV Infection in Children	1592U89, AZT, 3TC	84
New	159	HIV Infection in Children	CD4-IgG2	84
	160	Infant Immune Response	Pneumococcal Conjugate Vaccine	85
	161	Bacterial Infection Prevention in Children	Antibiotics	85
	162	Congenital CMV Infection	Ganciclovir	86
	163	Growth and Nutritional Status in Infants	Formula	86
	164	Herpes Simplex/Zoster Infections in Children	Valacyclovir	87
	165	Measles Vaccine in Children	Measles vaccine	87
	166	Varicella Vaccine in Children	Varicella Vaccine	88
	167	HIV Infection in Children and Adolescents	Observational study	88
	168	HIV Infection in Pregnant Women	Observational study	89

New

1. HIV Infection: CSF Viral Load

Title:

Cerebrospinal Fluid Analysis of HIV-1 Viral Burden in HIV-1-Infected Subjects: Response to Antiretroviral Therapy

Type of treatment:

None: observational, natural history

Purpose:

To see what effect antiretroviral therapy has on the amount of HIV in the spinal fluid and to see what effect it has on neurological function.

About the study:

Patients in this study will have two lumbar punctures (spinal taps) at the beginning of the study and three more spinal taps during the course of one year. Spinal taps consist of a needle being passed into the spinal column between vertebra and having some fluid removed. Patients are paid $75 for the first spinal tap, $100 for the second, and $125 for the next three. Blood tests and neurological exams will also be performed at weeks 16 and 52. The study lasts one year.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Patients must be starting or changing antiretroviral therapy at the time of study entry

Not allowed:

- Brain mass lesions
- Neurological disorders such as cryptococcal meningitis, toxoplasmosis, severe psychiatric disorder or active drug or alcohol abuse
- Noncompliance with antiretroviral medications

Location:

SFGH Department of Neurology
Richard W. Price, MD
(415) 206-3208

New

2. HIV Infection: Genotypic Antiretroviral Resistance Testing (GART)

Title:

CPCRA 046: A Pilot Study of the Short-Term Effects of Antiretroviral Management Based on Plasma Genotypic Antiretroviral Resistance Testing (GART) Compared with Antiretroviral Management Without Plasma GART

Type of treatment:

None: observational, natural history

Purpose:

To see the effects of doctors using genotypic antiretroviral resistance testing (GART) to manage patients' antiretroviral therapy.

About the study:

Patients are assigned by chance to one of two groups. The doctors treating patients in the first group will be given the results from GART and will use the results to make changes in their patients' antiretroviral therapy. Doctors treating patients in the second group will not be given the results from GART but will use current tests, such as CD4 cell count and HIV RNA viral load measurements to make decisions about changing their patients' antiretroviral medications. After two initial visits, study visits are once a month and the study lasts three months

Required:

- CD4 cell (T-cell) range: between 50 and 500
- Viral load range: more than 50,000 copies by bDNA more than 25,000 copies by PCR
- Must currently be on one of the following therapies for at least 16 weeks: AZT + 3TC + Indinavir AZT + 3TC + Saquinavir AZT + 3TC + Ritonavir d4T + 3TC + Indinavir
- HIV positive
- At least 13 years old
- At least 18 months of cummulative antiretroviral therapy
- Must have had a large rise in HIV RNA viral load or a previously documented HIV RNA level of undectectable while on current therapy (as above)

Not allowed:

- Patients unwilling or unable to change their antiretroviral therapy
- Any vaccination or illness within two weeks prior to study entry and throughout the study
- Patients who have had access to previous genotypic or phenotypic testing results

Location:

Community Consortium
To be arranged through physician-see page 119
(415) 476-9554

New

3. HIV Infection: Fortovase, Ritonavir, Delavirdine, DMP-266, Adefovir Dipivoxil

Title:

ACTG 359: Activity of the Soft Gelatin Capsule of Saquinavir (SQVsgc) in Combination with Ritonavir or Nelfinavir and Combinations of Delavirdine, and/or Adefovir Dipivoxil in HIV-Infected Subjects with Prior Indinavir Use and Viral Loads Between 2,000 and 200,000 Copies HIV RNA/mL

Type of treatment:

Adefovir dipivoxil: antiretroviral, reverse transcriptase inhibitor, nucleotide analog
Fortovase: antiretroviral, protease inhibitor
Ritonavir: antiretroviral, protease inhibitor
DMP-266: antiretroviral, non-nucleoside reverse transcriptase inhibitor (NNRTI)
Delavirdine: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI

Purpose:

To compare the safety, tolerance, toxicity and effectiveness of ritonavir and nelfinavir; adefovir dipivoxil and delavirdine; and their combinations in treating HIV infection.

About the study:

All patients will take soft gel saquinavir (Fortovase) and be assigned by chance to receive ritonavir or nelfinavir in addition to soft gel saquinavir (Fortovase). Patients will know which they are receiving. Patients are further assigned by chance to receive delavirdine and/or adefovir dipivoxil. Neither patients nor their doctors will know which of these drugs (or placebo) they are taking until the study ends. Study visits are once a month for the first four months, then again at week 24. Patients who have not demonstrated a decrease in viral load at week 16 will end the study at week 24. Those patients who have had a decrease in their HIV viral load may continue on study medications for an additional 24 weeks. The study lasts at least 24 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: between 2,000 and 200,000 copies/mL
- HIV positive
- More than six months of indinavir (Crixivan) therapy prior to study entry
- At least 16 years old

Not allowed:

- Prior use of NNRTIs (such as delavirdine, nevirapine, DMP-266), saquinavir soft gel capsule (Fortovase), nelfinavir, 141W94 or adefovir dipivoxil
- More than two weeks total use of ritonavir and/or saquinavir hard gel capsules (Invirase)
- Use of any immunomodulators, such as interleukins or interferons, or investigational drugs within 30 days of study entry
- Any active infection requiring acute treatment within 30 days prior to study entry
- Any cancers, including KS, requiring chemotherapy
- Women who are pregnant or breastfeeding

Location:

UCSD Treatment Center
Anne French, RN
(619) 543-8080 ext. 238

LAC-USC Medical Center
Frances Canchola, RN
(213) 343-8281

UCSF AIDS Program at SFGH/ACTU
Kathy Dybeck, RN
(415) 476-9296 ext. 353

Kaiser San Francisco - HIV Research Unit
Susan Kirk, RN
(415) 202-3484

New

4. HIV Infection: SCH 52000 (Interleukin 10)

Title:

C96-346: A Phase IB Study of the Safety, Tolerance and Activity on Plasma Viremia of Multiple Dose SC rhuIL-10 Administration in HIV Positive Individuals With CD4 Cell Counts of > 200/mm^3

Type of treatment:

SCH 52000: immune modulator

Purpose:

To see if SCH 52000 (Interleukin 10) is safe and well-tolerated and to see how it is processed by the body. To see if SCH 52000 is capable of fighting HIV.

About the study:

Patients are assigned by chance to receive SCH 52000 or placebo. Both SCH 52000 and placebo are given by injection under the skin. Patients will receive injections either every day or three times a week for four weeks. Neither patients nor their doctors will know which they are receiving until the study ends. There will be two 24-hour study visits; one on the first day and last day of study treatment. Regular study visits are every two weeks. The study lasts about ten weeks.

Required:

- CD4 cell (T-cell) range: more than 200
- Viral load range: at least 1,500 copies/mL
- HIV positive
- Between 18 and 55 years old
- If on antiretroviral therapy, must have been on stable (no changes) therapy for at least four weeks prior to study entry and throughout the study
- Weigh less than 230 lbs.

Not allowed:

- Women who are pregnant or breastfeeding
- Any cancers, including KS
- Any chemotherapy within the last year
- Any use of IL-10 within eight weeks prior to study entry
- Use of any immunomodulators (such as interleukins, interferons, IVIG, GM-CSF, thalidomide) within eight weeks of study entry
- Use of any HIV vaccines within the past three months

Location:

UCSF AIDS Program at SFGH/ICTG
Dorie Heeren, RN
(415) 476-9296, ext. 305

New

5. HIV Infection: PMPA

Title:

GS97-901: A Phase I/II Randomized, Double-Blind, Placebo-Controlled Study of the Safety, Tolerance, Pharmacokinetics, and anti-HIV Activity of PMPA Prodrug Administered Orally to HIV-Infected Patients With CD4 Cell Counts of 200 Cells/mm^3 or More

Type of treatment:

PMPA: antiretroviral, nucleoside analog

Purpose:

To see if PMPA prodrug is safe, well-tolerated and if it has any anti-HIV activity. To see how PMPA prodrug is processed by the body.

About the study:

Patients are assigned by chance to receive one of five doses of PMPA prodrug or to receive placebo. Neither patients nor their doctors will know which they are receiving until the study ends. Both PMPA prodrug and placebo are pills and taken by mouth once a day. Patients will be required to stay overnight in the hospital three times (48 hours each). Study visits are every three days. The study lasts seven weeks. Patients will be paid for completing this study.

Required:

- CD4 cell (T-cell) range: at least 200
- Viral load range: at least 10,000 copies/mL
- HIV positive
- Between 18 and 60 years old

Not allowed:

- Active, serious infections requiring antibiotics
- Women who are pregnant or breastfeeding
- Active cardiac disease, such as ischemia, congestive heart failure or arrhythmia
- More than 14 days use of bis-POM PMEA
- Any cancers other than basal cell carcinoma or KS of the skin
- Concurrent use of any antiretroviral therapy, interferons, cidofovir, foscarnet, ganciclovir, ketoconazole, itraconazole, fluconazole, INH, rifampin, rifabutin, clarithromycin, azithromycin or chemotherapy. Any of these medications must be discontinued for at least two weeks prior to study entry
- Current hepatitis B
- Active drug or alcohol abuse

Location:

UCSF AIDS Program at SFGH/ICTG
Jenny Sitrin
(415) 476-9296 ext. 311

New

6. HIV Infection: Indinavir, 3TC, Delavirdine, AZT, d4T

Title:

ACTG 370: Virologic and Immunologic Activity of Continued Lamivudine (3TC) Versus Delavirdine (DLV) in Combination with Indinavir (IDV) and Zidovudine (ZDV) or Stavudine (d4T) in 3TC-Experienced Subjects (ACTG 306 Rollover Study)

Type of treatment:

d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Delavirdine: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Indinavir: antiretroviral, protease inhibitor

Purpose:

To compare the effects of two AZT-containing drug combinations to see how many people have an undetectable amount of HIV virus in the blood at both weeks 20 and 24. To compare the safety of each of the three drug combinations.

About the study:

Patients will be divided into two groups. Group A patients have an undetectable level of virus in their blood at the beginning of the study and will remain on the same drug combination they were taking in ACTG 306. If patients in Group A show a detectable amount of

HIV during the study, they will be switched to Group B. Patients in Group B have a detectable amount of HIV virus in their blood at the beginning of the study and will receive a new drug combination. Patients who are currently taking AZT and 3TC will be assigned to take indinavir plus delavirdine plus d4T. Patients who are taking ddI or d4T plus 3TC will be assigned by chance to receive AZT, 3TC plus indinavir OR AZT, delavirdine plus indinavir. Patients will take study medications for 24 weeks. Study visits are once a month for the first four months, then one visit at 6 months. Additionally, patients in Group B will have additional blood drawn at weeks 4 and 16 and an additional study visit at week 20. Before the end of the study, patients and their doctors will be told which drugs they took in ACTG 306 and in ACTG 370. The study lasts 24 weeks.

Required:

- CD4 cell (T-cell) range: at least 200
- Viral load range: not applicable
- HIV positive
- At least 18 years old
- Patients completing ACTG 306 who remain on blinded therapy through the extension period **OR** patients with at least 6 months of ddI/3TC or d4T/3TC combination therapy and have HIV RNA levels of >500 copies/mL

Not allowed:

- Unexplained fever (more than 101.3 F) for seven consecutive days, or chronic diarrhea defined as more than three liquid stools per day persisting for 15 days, within 30 days of study entry
- Acute therapy for any infection within 14 days of study entry
- Acute hepatitis within 30 days of study entry
- Past or current pancreatitis
- Severe peripheral neuropathy
- Past use of NNRTIs (such as delavirdine or nevirapine) and protease inhibitors
- Use of EPO, G-CSF or GM-CSF within 30 days of study entry
- Use of interferons, interleukins or vaccines within 30 days of study entry
- Any previous induction or maintenance therapy with foscarnet

Location:

UCSD Treatment Center
Anne French, RN
(619) 543-8080 ext. 238

New

7. HIV Infection: ddI, d4T

Title:

A1454-143: A Randomized, Double-Blind Study of the Antiviral Activity of Once-Daily and Twice-Daily Dosing of Didanosine in Combination with Twice-Daily Dosing of Stavudine in HIV-Infected Patients

Type of treatment:

ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To compare the antiviral activity of once a day dosing to twice a day dosing of ddI.

About the study:

All patients will take stavudine (d4T). Patients are assigned by chance to receive ddI once a day or twice a day. Neither patients nor their doctors will know which dose of ddI they are taking until the study ends. Patients assigned to take ddI once a day will take ddI in the morning and ddI placebo in the evening. Study visits are every two weeks for the first two months, then once a month. The study lasts at least 12 weeks. Some study sites may pay patients for completing this study.

Required:

- CD4 cell (T-cell) range: at least 100
- Viral load range: at least 10,000 copies/mL
- HIV positive
- At least 18 years old

Not allowed:

- Past use of any antiretrovirals
- Active AIDS-defining opportunistic infections
- Active alcohol or substance abuse
- Women who are pregnant or breastfeeding
- Past or current pancreatitis
- Any hepatitis within 30 days of study entry
- Severe peripheral neuropathy
- Uncontrolled diarrhea, defined as six or more stools/day for seven or more consecutive days within 30 days of study entry

Location:

Shared Medical Research Foundation
Karen Zunigar
(818) 345-2172

Center for Special Immunology - Irvine
Sandra Casserella, RN
(714) 753-0670

New

8. HIV Infection: SCH 52000 (Interleukin 10) 2

Title:

C96-406: A Phase IB Study of the Safety, Tolerance and Activity on Plasma Viremia of Multiple Dose SC rhuIL-10 Admistration in HIV-Positive Individuals with CD4 Positive T Cell Counts of <50/mm^3

Type of treatment:

SCH 52000: immune modulator

Purpose:

To see if SCH 52000, interleukin 10, can suppress the HIV virus in the blood and to see how long the suppression lasts. To see if IL-10 is safe and effective for treating HIV infection.

About the study:

Patients are assigned by chance to receive one of three doses of IL-10 or placebo either daily or three times a week for four weeks. Neither patients nor their doctors will know which they are receiving until the study ends. IL-10 and its placebo are given as injections under the skin. Pateints will be taught how to give themselves injections. There are two screening visits and patients will be required to stay overnight for the first and last day of drug dosing. Patients will have study visits once a week during the four-week drug phase, then every other week for an additional four weeks of follow-up. The study lasts about two months.

Required:

- CD4 cell (T-cell) range: below 50
- Viral load range: at least 1,500 copies/mL
- HIV positive
- Between 18 and 55 years old
- If on antiretroviral therapy, must have stable (no changes) treatment for at least four weeks prior to study entry and throughout the study
- Weigh less than 230 lbs.

Not allowed:

- Women who are pregnant or breastfeeding
- Use of any investigational drug within 30 days prior to study entry
- Any cancers including KS
- Any chemotherapy within the past year
- Use of IL-10 within eight weeks prior to study entry
- Current opportunistic infections except fungal infections of the skin and oral thrush
- Use of any immunomodulators such as interferons or interleukins within eight weeks prior to study entry
- Use of any HIV vaccines within three months of study entry

Location:

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

New

9. HIV Infection: Delavirdine, Nelfinavir, ddI, d4T

Title:

M/3331/0073: Am Open Label Randomized Study of Delavirdine Mesylate Plus Nelfinavir, Didanosine and Stavudine in Triple and Quadruple Treatment Regimens in HIV-Infected Individuals

Type of treatment:

d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Nelfinavir: antiretroviral, protease inhibitor
Delavirdine: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI

Purpose:

To test the safety, tolerance and effectiveness of combinations of three or four drugs.

About the study:

Patients are assigned by chance to one of four groups: delavirdine + nelfinavir + d4T; delavirdine + nelfinavir + ddI; delavirdine + nelfinavir + d4T + ddI; delavirdine + d4T + ddI. Patients in three of the groups will be taking three medications while patients in the fourth group will be taking four. Patients will know which drugs they are taking. All medications are pills and taken by mouth. Study visits are once a week for the first month, then once a month for two months, then every two months. The study lasts 24 weeks and patients may choose to continue for another 24 weeks.

Required:

- CD4 cell (T-cell) range: at least 50
- Viral load range: at least 20,000 copies/mL
- HIV positive
- At least 14 years old

Not allowed:

- More than six months total use of ddI
- Prior use of d4T or any NNRTIs, such as delavirdine, nevirapine, DMP-266, atevirdine, loviride or HBY 097
- Prior use of any protease inhibitor
- Use of any investigational drug or immunomodulators, such as interferons or interleukins, within 21 days of study entry
- Use of any HIV vaccines within 21 days of study entry
- Active opportunistic infections within one month of study entry
- Use of rifampin or rifabutin within 21 days of study entry
- Use of Hismanal, Seldane, Xanax, Halcion or Propulsid within 7 days of study entry and throughout the study
- Women who are pregnant or breastfeeding
- Active alcohol or substance abuse
- Cirrhosis of the liver

Location:

ViRx., Inc. - Palm Springs
Angela Wilder
(760) 864-6266

UC Davis Medical Center
Michael Peterson
(916) 734-8282

New

10. HIV Infection: Delavirdine, Indinavir, AZT, 3TC

Title:

M/3331/0074: An Open Label Study of Delavirdine Mesylate in Triple and Quadruple Combinations with Zidovudine, Indinavir and Lamivudine in HIV-Infected Individuals

Type of treatment:

Delavirdine: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI
3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Indinavir: antiretroviral, protease inhibitor

Purpose:

To test the safety, tolerability and effectiveness of combinations of three or four drugs.

About the study:

Patients are assigned by chance to one of four groups: delavirdine + indinavir + AZT; delavirdine + indinavir + 3TC; delavirdine + indinavir + AZT + 3TC; indinavir + AZT + 3TC. Patients in three of the groups will be taking three medications while patients in the fourth group will be taking four. Patients will know which medications they are taking. All medications are pills and taken by mouth. Study visits are once a week for the first month, then once a month for two months, then every two months. The study lasts 24 weeks and patients may choose to continue for another 24 weeks.

Required:

- CD4 cell (T-cell) range: at least 50
- Viral load range: at least 20,000 copies/mL
- HIV positive
- At least 14 years old

Not allowed:

- More than six months use of AZT
- Prior use of 3TC or any NNRTIs, such as delavirdine, nevirapine, DMP-266, atevirdine, loviride or HBY 097
- Prior use of any protease inhibitors
- Use of any investigational drugs or immunomodulators, such as interferons or interleukins, within 21 days of study entry
- Use of any HIV vaccines within 21 days of study entry
- Active opportunistic infections within one month of study entry
- Use of rifampin or rifabutin within 21 days of study entry
- Use of Hismanal, Seldane, Xanax, Halcion or Propulsid within 7 days of study entry and throughout the study
- Women who are pregnant or breastfeeding
- Active alcohol or substance abuse
- Cirrhosis of the liver

Location:

UC Davis Medical Center
Michael Peterson
(916) 734-8282

New

11. HIV Infection: 141W94, AZT, 3TC, Indinavir, Nevirapine, d4T

Title:

ACTG 373: A Phase II Study of 1) 141W94/VX-478 Plus 3TC Plus ZDV or 2) Indinavir Plus Nevirapine Plus 3TC Plus Stavudine in Subjects Previously Treated with 141W94/VX-478

Type of treatment:

d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Indinavir: antiretroviral, protease inhibitor
141W94: antiretroviral, protease inhibitor
Nevirapine: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI
3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see how many patients in both study groups have HIV viral loads levels that either remain below the level of detection or decrease below the level of detection during the 96 weeks of treatment. To see if these drugs are safe when used in combination.

About the study:

There are two groups of patients in this study. Group A patients have less than 500 copies/mL of HIV RNA while taking antiretrovirals that included 141W94/VX-478 and will take 141W94/VX-478, 3TC and AZT (or d4T for patients who cannot take AZT). Patients in Group B have more than 500 copies/mL of HIV RNA or those who could not tolerate 141W94/VX-478. Patients in Group B will take indinavir, nevirapine, 3TC and d4T. All study drugs are pills and taken by mouth. All patients will know which drugs they are taking. Patients in Group A who do not do well on treatment may move over to Group B. Patients in Group B who do not do well on treatment will be discontinued from the study. Study visits are every two weeks for the first month, then once a month until the end of the study. The study lasts 96 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- Currently taking 141W94/VX-478 or have failed (defined as more than 500 copies/mL HIV RNA after 20 weeks of treatment) or cannot tolerate 141W94/VX-748
- At least 13 years old

Not allowed:

- Women who are pregnant or breastfeeding
- Active opportunistic infections within 14 days prior to study entry **(Group A ONLY)**
- Any cancer requiring chemotherapy, other than minimal KS of the skin **(Group B ONLY)**

Location:

LAC-USC Medical Center
Gil Clemente, RN
(213) 343-8284

New

12. HIV Infection: 1592U89, Indinavir, AZT, 3TC

Title:

CNAA/B3005: A Phase III Randomized, Double-Blind, Multicenter Study to Evaluate the Safety and Efficacy of 3TC/ZDV/1592U89 and 3TC/ZDV/IDV in HIV-1 Infected Antiretroviral Therapy Naive Subjects

Type of treatment:

AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Indinavir: antiretroviral, protease inhibitor
1592U89: antiretroviral

Purpose:

To measure the antiviral response of 3TC/AZT/1592U89 versus 3TC/AZT/Indinavir and to compare the safety and tolerance of the two combinations.

About the study:

All patients will take the AZT/3TC combination tablet, called combivir, and are assigned by chance to receive 1592U89 (abacavir) or indinavir (Crixivan). Neither patients nor their doctors will know which they are taking until the study ends. Study visits are every two weeks for the first month, then once a month until week 48, then every two months. Patients who complete the study may have the option to switch to open-label (real) 1592U89 and receive it until it is licensed in their country. The study lasts at least 48 weeks.

Required:

- CD4 cell (T-cell) range: at least 100
- Viral load range: at least 10,000 copies/mL
- HIV positive
- At least 16 years old
- Must be antiretroviral treatment naive

Not allowed:

- Past use of any antiretroviral treatment
- Active AIDS-defining illnesses
- Women who are pregnant or breastfeeding
- Current alcohol or substance abuse
- Use of radiation or chemotherapy within 30 days of study entry or the need for such treatment during the study
- Use of any HIV vaccines within 90 days of study entry
- Use of any immunomodulators, such as interferons or interleukins, within 30 days of study entry
- Patients requiring foscarnet treatment
- Pancreatitis or hepatitis within the past six months

Location:

Harbor-UCLA Medical Center
Connie Kapeluck
(310) 222-5291

AIDS Research Alliance
Corie Castro
(310) 358-2429

New

13. HIV Infection: S-1153

Title:

9616T0311: Phase I Trial of S-1153 in Patients with HIV Infection

Type of treatment:

S-1153: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI

Purpose:

To see if S-1153, a new non-nucleoside reverse transcriptase inhibitor, is safe and well-tolerated in patients infected with HIV. To determine the maximum tolerated dose and to see how S-1153 is processed by the body.

About the study:

Patients are assigned by chance to receive one of three doses of S-1153. All patients will receive real S-1153; there are no placebos in this study. Patients will come to the clinic on the first day and remain there for about 10 hours for testing. Study visits are once a week for three weeks and last 1-2 hours. At the end of the fourth week, patients will be admitted to the hospital for a 26-hour stay for blood tests and physical exams. There is one last follow-up visit three weeks after the last dose of S-1153. This visit will last about one hour. S-1153 is in pill form and taken by mouth. The study lasts about one and a half months. Patients will be paid $500 for completing the study.

Required:

- CD4 cell (T-cell) range: between 50 and 550
- Viral load range: not applicable
- HIV positive
- Between 18 and 70 years old
- Patients with less than 200 T-cells must take medicine to prevent PCP

Not allowed:

- Use of any NNRTIs, such as delavirdine or nevirapine, or any protease inhibitors within 30 days of study entry
- Active opportunistic infections
- Use of chemotherapy, radiation therapy, or interferons within three weeks of study entry
- Women who are pregnant or breastfeeding

Location:

HIVCare, Saint Francis Memorial Hospital
Sal Iacopelli
(415) 353-6298

New

14. HIV Infection: Indinavir, DMP-266

Title:

Merck 067: A Multicenter, Open-Label, Randomized, 48-Week Pilot Study to Evaluate the Activity, Safety and Pharmacokinetics of Indinavir 1200mg q12h and DMP-266, 300mg q12h versus Indinavir 1000mg q8h and DMP-266 600mg qhs

Type of treatment:

Indinavir: antiretroviral, protease inhibitor
DMP-266: antiretroviral, non-nucleoside reverse transcriptase inhibitor (NNRTI)

Purpose:

To see which doses of indinavir and DMP-266 are most effective in lowering the amount of HIV virus in the blood. To see if these dosages are safe and how they are processed by the body.

About the study:

All patients will take indinavir and DMP-266. Patients are assigned by chance to take one of two doses of indinavir and DMP-266. Patients will know which dose they are receiving. All medications are pills and taken by mouth. Study visits are once a month and the study lasts about one year.

Required:

- CD4 cell (T-cell) range: more than 100
- Viral load range: more than 10,000 copies/mL
- HIV positive
- At least 18 years old
- Patients who are taking any antiretroviral medications must discontinue them at least two weeks before entering the study

Not allowed:

- Prior use of any protease inhibitors
- Women who are pregnant or breastfeeding

Location:

UCSF AIDS Program at SFGH/ICTG
Doug Raggett, RN
(415) 476-9296, ext. 312

New

15. HIV Infection: 141W94, Indinavir

Title:

PROA/B3006: A Phase III Trial to Compare the Safety and Antiviral Efficacy of 141W94 with Indinavir in Combination with NRTI Therapy in NRTI-Experienced, PI-Naive HIV-1-Infected Patients

Type of treatment:

141W94: antiretroviral, protease inhibitor
Indinavir: antiretroviral, protease inhibitor

Purpose:

To compare 141W94 with indinavir (Crixivan) when combined with nucleoside analogs. To see which combination best lowers HIV viral load to an undetectable level.

About the study:

Patients are assigned by chance to receive 141W94 or indinavir to take with nucleoside reverse transcriptase inhibitors (NRTI) such as AZT, ddI, ddC, 3TC or d4T. Patients will know which drugs they are taking. All medications are taken by mouth. There are 20 study visits and the study lasts one year. 141W94 and indinavir will be paid for by the study but patients are financially responsible for NRTI medications.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: must be detectable (more than 400 copies/mL)
- HIV positive
- Must have been on stable (no changes) antiretroviral therapy for at least 12 weeks prior to study entry

Not allowed:

- Past use of any protease inhibitors
- Women who are pregnant or breastfeeding

Location:

AIDS Healthcare Foundation
Heather Churchill, RN
(213) 913-3953

East Bay AIDS Center
Nancy Orcutt, RN, MS
(510) 204-1291

New

16. HIV Infection: Indinavir, AZT, 3TC

Title:

Merck 069-00: A Multicenter, Open-Label, Randomized, 24-Week Study to Compare the Safety and Activity of Indinavir Sulfate, 800mg q8h Versus 1200 mg q12h, in Combination With Zidovudine and 3TC

Type of treatment:

AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Indinavir: antiretroviral, protease inhibitor
3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To compare the antiviral activity of 1200 mg of indinavir (Crixivan) every 12 hours to 800 mg of Crixivan every 8 hours, when taken with AZT and 3TC.

About the study:

All patients will take AZT and 3TC and are assigned by chance to take 1200 mg of Crixivan every 12 hours or 800 mg every 8 hours. Patients will know which dose schedule they are on. Study visits are once a month and patients will take study medication for 24 weeks.

Required:

- CD4 cell (T-cell) range: at least 100
- Viral load range: at least 10,000 copies/mL
- HIV positive
- At least 16 years old
- Patients currently on antiretroviral medications must discontinue them for at least two weeks prior to study entry

Not allowed:

- Prior use of any protease inhibitors or 3TC
- Women who are pregnant or breastfeeding
- Use of any investigational drugs, nonlicensed antiviral drugs, immunomodulators within 30 days of study entry
- Any cancers requiring chemotherapy
- Current use of ketoconazole, itraconazole, rifampin or rifabutin
- Active alcohol or substance abuse
- Active opportunistic infections or cancers
- Current hepatitis

Location:

Kaiser San Francisco - HIV Research Unit
Gretchen Van Raalte, RN, MS
(415) 202-3482

New

17. HIV Infection: CD4-zeta Gene Therapy

Title:

A-9604: A Phase II Study of Autologous CD4-Zeta Gene-Modified T-Cells in HIV-Infected Patients with Undetectable Plasma Viremia on Combination Antiretroviral Drug Therapy

Type of treatment:

CD4-Zeta T Cells: gene therapy

Purpose:

To see if gene-modified T-cells are safe when combined with antiretroviral therapy and to see if they have any effect on delaying the increase in HIV viral load.

About the study:

Before infusion, patients will give blood samples from which T-cells are removed. Two human genes, CD4 and zeta, which occur naturally in T-cells, are combined to produce the CD4-zeta gene. The CD4-zeta gene is added to the patients T-cells. The modified T-cells are then given back to the patient as an infusion into a vein. Patients will have an infusion once a week for two weeks. Study visits are once a week and the study lasts from three to six months.

Required:

- CD4 cell (T-cell) range: at least 100
- Viral load range: undetectable
- HIV positive Patients must be on stable (no changes) antiretroviral therapy for at least eight weeks prior to study entry and continue this therapy for the duration of the study

Not allowed:

- Current AIDS-defining opportunistic infection or cancer, except KS of the skin
- Prior use of gene therapy

Location:

ViRx, Inc.
Debbie Hildebrandt
(415) 353-5623

AIDS Community Research Consortium
Sharon O'Leary, RN
(650) 364-6563

New

18. HIV Infection: Cyclosporin

Title:

A Pilot Study of Cyclosporin-A in Modulating Immune System Activation in HIV-1 Disease

Type of treatment:

Cyclosporin: immune suppresant

Purpose:

To see if cyclosporin is safe and to see if it can help to lower the immune system activation that accompanies HIV disease.

About the study:

All patients will receive cyclosporin. Cyclosporin is a pill and taken by mouth. After four weeks, patients will take a higher dose for another four weeks. Study visits are once a week and the study lasts 12 weeks. Patients wil be paid $10 for each study visit completed

Required:

- CD4 cell (T-cell) range: between 300 and 600
- Viral load range: not applicable
- HIV positive
- At least 18 years old
- Patients on antiretroviral therapy must discontinue use for at least 30 days prior to study entry and throughout the study

Not allowed:

- No exclusions

Location:

ViRx, Inc.
Debbie Hildebrandt
(415) 353-5623

New

19. HIV Infection: XQ-9302 (Chinese Herbs)

Title:

A Phase I/II Randomized, Double-Blind, Placebo-Controlled Study of XQ-9302, A Compound Comprised of 20 Uncharacterized Chinese Botanicals in HIV-1 Infected Patients

Type of treatment:

XQ-9302: Chinese herbs

Purpose:

To see if XQ-9302 is safe to take and to see if it has any effect on CD4 cell (T-cells) and HIV viral load.

About the study:

Patients are assigned by chance to receive XQ-9302 or placebo. Neither patients nor their doctors will know which they are receiving until the study ends. XQ-9032 and its placebo are capsules and taken by mouth four times a day. Patients will take study drug for eight weeks. After eight weeks, those patients who took placebo will take open label (real) XQ-9302 for an additional eight weeks if no bad side effects have been observed. Study visits are once a week and the study lasts at least 20 weeks.

Required:

- CD4 cell (T-cell) range: at least 200
- Viral load range: at least 5,000 copies/mL
- HIV positive
- At least 18 years old
- If on antiretroviral therapy, must have been on stable (no changes) therapy for at least three months and make no changes throughout the study. The first six patients to enroll will not be on any antiretroviral therapy.

Not allowed:

- Current opportunistic infections or cancers including KS of the skin
- Women who are pregnant or breastfeeding
- Prior use of ritonavir
- Active alcohol or substance abuse
- Use of any other herbal product or compound for at least two weeks prior to and during the study
- Use of any immunomodulators, such as interleukins, interferons, corticosteroids, chemotherapy, within 12 weeks of study entry
- Loss of more than 10% of body weight in the six months prior to study entry
- Any vaccination or flu shot within three months of study entry
- Current hepatitis or syphilis

Location:

AIDS Research Alliance
Corie Castro
(310) 358-2429

New

20. HIV Infection: Nelfinavir, Hydroxyurea, d4T, ddI

Title:

BMS062: A Pilot, Open-Label Study of HIV Therapy with d4T, ddI, Nelfinavir and Hydroxyurea in Subjects with Early Asymptomatic HIV Infection

Type of treatment:

Hydroxyurea: cytotoxic chemotherapy
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Nelfinavir: antiretroviral, protease inhibitor
ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see what effect this combination of drugs has on reducing the amount of HIV virus in the blood and in body tissues.

About the study:

All patients will take d4T, ddI, nelfinavir and hydroxyurea; there are no placebos in this study. All medications are pills and taken by mouth. Study visits are once a month and the study lasts 96 weeks. Patients will be required to have a lymph node biopsy.

Required:

- CD4 cell (T-cell) range: more than 500
- Viral load range: not applicable
- HIV positive
- Must be recently infected

Not allowed:

- Past use of any antiretroviral medications
- Women who are pregnant or breastfeeding

Location:

UCSF AIDS Program at SFGH/ICTG
Doug Raggett, RN
(415) 476-9296, ext. 312

New

21. HIV Infection in Newly Seroconverted: VIRACEPT, AZT, 3TC

Title:

AG1343-512: A Phase II, Open-Label, Pilot Study to Assess the Durability of HIV-1 Replication Inhibition in Patients with Primary HIV Infection (Seroconversion Syndrome) Who are Treated with VIRACEPT Plus Zidovudine (ZDV) and Lamivudine (3TC)

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Nelfinavir: antiretroviral, protease inhibitor

Purpose:

To see the effect of Viracept, AZT and 3TC on HIV viral load in patients who have recently tested positive for the HIV antibody.

About the study:

All patients will take Viracept, AZT and 3TC; there are no placebos in this study. All medications are pills and taken by mouth. Study visits are every two to four weeks and the study lasts about one year.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: not applicable
- Must have recently tested HIV antibody positive

Not allowed:

- Women who are pregnant or breastfeeding
- Past use of any antiretroviral medications

Location:

UCSF AIDS Program at SFGH/ICTG
Doug Raggett, RN
(415) 476-9296, ext. 312

New

22. HIV Infection in Newly Seroconverted: d4T, ddI, Nelfinavir, Hydroxyurea

Title:

BMS063: A Pilot, Open-Label Trial of HIV Therapy with d4T, ddI, Nelfinavir and Hydroxyurea in Subjects With Recent HIV Infection

Type of treatment:

Hydroxyurea: cytotoxic chemotherapy
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Nelfinavir: antiretroviral, protease inhibitor

Purpose:

To see if this four-drug combination can lower the amount of HIV virus to an undectable level.

About the study:

All patients will receive d4T, ddI, nelfinavir (also called Viracept) and hydroxyurea; there are no placebos in this study. All medications are pills and taken by mouth. Study visits are once a month and the study lasts 96 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: not applicable
- Must have tested HIV positive in the past three months

Not allowed:

- Past use of any antiretroviral medications
- Women who are pregnant or breastfeeding

Location:

UCSF AIDS Program at SFGH/ICTG
Doug Raggett, RN
(415) 476-9296, ext. 312

New

23. HIV Infection: I592U89 (abacavir)

Title:

CNAA-B3008: A 1592U89 Open Label Protocol for Adult Patients with HIV Infection

Type of treatment:

1592U89: antiretroviral

Purpose:

To provide 1592U89 to patients who have limited treatment options.

About the study:

All patients will receive 1592U89. Patients must be seen by their doctors at least every two months for data collection. Patients will be in this study until their doctors feel they are no longer receiving benefits or until the drug is FDA-approved and marketed in the United States.

Required:

- CD4 cell (T-cell) range: less than 100
- Viral load range: more than 30,000 copies/mL
- At least 13 years old
- HIV positive
- Past treatment with at least two NRTIs (such as AZT, ddI, ddC, d4T or 3TC) and one protease inhibitor **OR** have attempted at least two different treatments in the past, one of which contained a protease inhibitor. Patients must be intolerant to one NRTI and one protease inhibitor

Not allowed:

- Women who are pregnant or breastfeeding
- Active alcohol or substance abuse
- Current liver or kidney failure, diabetes, congestive heart failure, cardiomyopathy or other cardiac dysfunction

Location:

East Bay AIDS Center
Nancy Orcutt, RN, MS
(510) 204-1291

Kaiser Permanente - Los Angeles
Rosa Kawahira, RN
(213) 783-8172

New

24. HIV and CMV Infection: Viral Load

Title:

ACTG 360: Human Immunodeficiency Virus (HIV) and Cytomegalovirus (CMV) Viral Burden and Development of CMV End-Organ Disease: A Prospective Study in HIV-Infected Individuals

Type of treatment:

None: observational, natural history

Purpose:

To see what relationships exist between HIV viral load and the risk of CMV disease; CMV viral load and the risk of CMV disease; and CMV viral load and HIV viral load.

About the study:

This is an observational study for patients who are HIV infected and also CMV positive who have not had any symptoms of CMV disease at study entry. Patients will have study visits at baseline and every eight weeks. Blood samples will be taken every 16 weeks. Patients will be in this study for three years or until they develop CMV disease. Some locations may pay patients for their participation.

Required:

- CD4 cell (T-cell) range: 50 or less
- Viral load range: not applicable
- HIV positive
- At least 13 years old
- Positive for CMV antibodies

Not allowed:

- Past CMV disease, such as retinitis or colitis

Location:

LAC-USC Medical Center
Gil Clemente, RN
(213) 343-8284

UCSF AIDS Program at SFGH/ACTU
Mary Payne, RN
(415) 476-9296, ext. 356

Harbor-UCLA Medical Center
Sandra Houston, LVN
(310) 222-5291

25. HIV Infection: Hydroxyurea, ddI, d4T

Title:

A Phase I/II Open-Label Study to Evaluate the Safety and Preliminary Efficacy of Hydroxyurea Alone or in Combination with ddI or ddI plus d4T in HIV-Infected Persons - Hydroxyurea Extended Treatment

Type of treatment:

d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Hydroxyurea: cytotoxic chemotherapy
ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see if hydroxyurea alone or in combination with ddI and/or d4T is safe and effective in fighting HIV.

About the study:

Patients are assigned by chance to receive one of three treatments: hydroxyurea alone, hydroxyurea plus ddI, or hydroxyurea plus ddI and d4T. All medications are pills taken by mouth. Patients and their providers will know which treatment they are receiving. Study visits are every four weeks and the study lasts 68 weeks. The study has been extended for six extra months of drug treatment with a two-month follow-up

Required:

- CD4 cell (T-cell) range: not specified
- Viral load range: not specified
- HIV positive
- At least 18 years old

Not allowed:

- Pancreatitis within the past two years
- Active opportunistic infections which require treatment during the course of the study
- Ever used d4T or ddI before
- Any experimental drugs within 21 days before starting the study
- Pregnant or breastfeeding women

Location:

Shared Medical Research Foundation
Vicky Ramirez
(818) 345-2172

26. HIV Infection: Hydroxyurea, ddI

Title:

ACTG 307: A Phase I/II Dosing Study of the Safety and Antiretroviral Activity of Hydroxyurea Alone and in Combination with ddI Compared to ddI Alone in Subjects with HIV Infection

Type of treatment:

ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Hydroxyurea: cytotoxic chemotherapy

Purpose:

To see if hydroxyurea alone, or ddI alone, or a combination of the two is a safe and effective treatment for HIV infection. To see which dose of hydroxyurea is safest and best tolerated when taken with ddI.

About the study:

Patients are assigned by chance to one of five different groups. Patients will receive either hydroxyurea alone, ddI alone, or a combination of both using two different doses of hydroxyurea. Neither patients nor their doctors will know which treatments they are taking until the study is over. Patients assigned to receive hydroxyurea alone will have the ddI placebo changed to active ddI after four weeks. After 12 weeks, patients are assigned by chance again to receive either one of two doses of open-label (real) hydroxyurea plus open-label (real) ddI for an additional 12 weeks. About three visits are required before starting the study; then study visits will occur every two weeks until week eight. After week eight, study visits will occur once a month until the end of the study. The study lasts 24 weeks but a week 28 post-study visit is required. On the day of study drug dosing and on the week two visit, patients should plan on spending some time at the clinic as six blood draws are required on those days.

Required:

- CD4 cell (T-cell) range: Between 200 and 700
- HIV positive
- Must stop all current antiretroviral therapy for 14 days before starting the study and remain off all therapy for the duration of the study
- At least 18 years old

Not allowed:

- Severe peripheral neuropathy
- Any use of ddI for more than two weeks
- Previous use of hydroxyurea
- Women who are pregnant or breastfeeding
- Active substance abuse which could interfere with the study
- Any cancers which will require chemotherapy within the next 24 weeks
- Past pancreatitis or current alcohol abuse
- Treatment with any vaccine or immunomodulators within the past 30 days
- Treatment with any blood transfusions, G-CSF, GM-CSF or EPO within the last 60 days

Location:

UCSD Treatment Center
Anne French, RN
(619) 543-8080 ext. 238

Harbor-UCLA Medical Center
Mario Guerrero
(310) 222-3848

Stanford University Medical Center
Pat Cain, RN
(650) 723-8292

27. HIV Infection: rhIL-12

Title:

ACTG 325: A Phase I Double-Blinded Trial of Recombinant Human Interleukin-12 (rhIL-12) in HIV-Infected Subjects With Less Than 50 CD4+ T Cells and Subjects With 300-500 CD4+ T Cells, Who Have No Evidence of Serious Ongoing Opportunistic Infections

Type of treatment:

Interleukin-12: immune modulator

Purpose:

To see how well interleukin-12 is tolerated and to see if it is safe and effective in treating HIV infection. To find out which of three different doses of rhIL-12 is safest to take.

About the study:

This is a dose-ranging study. Patients with less than 50 T-cells are assigned by chance to receive the lowest of three doses of interleukin-12 or placebo (Part A). If no bad side effects are seen, the next patients to enter the study are assigned by chance to receive the middle dose of interleukin-12 or placebo. If no bad side effects are seen at that dose, the third group of patients to enroll will receive the high dose of interleukin-12 or placebo. After this part of the study is completed, patients with 300 to 500 T-cells are assigned by chance to receive the highest dose of interleukin-12 which had no bad side effects or placebo (Part B). Interleukin-12 is given by injection under the skin. Injections are given twice a week. The study lasts four weeks.

Required:

- CD4 cell (T-cell) range:
  Part A: less than 50
  Part B: between 300 and 500
- Viral load range: not applicable
- Between 18 and 60 years old
- HIV positive
- Patients must have been on stable antiretroviral therapy for at least four weeks before study entry
- Must be willing to take drugs to prevent Pneumocystis carinii pneumonia (PCP) **(Part A only)**

Not allowed:

- Current antiretroviral therapy with ddC or d4T
- Past history of MAC, CMV or any invasive fungal disease (such as cryptococcosis, histoplasmosis, coccidiomycosis, etc.)
- Any use of interleukin-12 within the past 24 weeks
- Women who are pregnant or breastfeeding

Location:

UCSF AIDS Program at SFGH/ACTU
Carol Arri, RN
(415) 476-9296 ext. 351

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

Stanford University Medical Center
Jane Norris, PA
(650 723-2805

Kaiser San Francisco - HIV Research Unit
Susan Kirk, RN
(415) 202-3484

28. HIV Infection: GM-CSF

Title:

001.0012: A Phase III Randomized, Double-Blinded, Placebo-Controlled Trial of Recombinant Human Granulocyte-Macrophage Colony-Stimulating Factor (rhu GM-CSF in Patients With Advanced HIV Disease

Type of treatment:

GM-CSF: white blood cell stimulator

Purpose:

To see if GM-CSF (Leukine) can reduce the number of new or recurring AIDS-related infections over time.

About the study:

Patients are assigned by chance to receive injections of GM-CSF or placebo. GM-CSF and its placebo are given as injections into a muscle. Patients will be taught how to give themselves injections. Neither patients nor their doctors will know which they are receiving until the study ends. Injections are given three times a week. There is one screening visit and there will be eight study visits during the 24-week treatment period. The study lasts 24 weeks with the possibility of a 24-week extension.

Required:

- CD4 cell (T-cell) range: 50 or less. Patients with a history of a previous AIDS-defining opportunistic infection may have 100 or less
- Viral load range: not applicable
- HIV positive
- At least 16 years old
- Patients must be on stable antiretroviral therapy for at least four weeks prior to study entry

Not allowed:

- Use of other investigational immunomodulators or cytokines, other than erythropoietin
- Any radiation or chemotherapy within two weeks prior to study entry **OR** the need for such during the study

Location:

Center for Special Immunology - Beverly Hills
Chris Rice, RN
(310) 289-6020

ViRx, Inc.
Debbie Hildebrandt
(415) 353-5623

AIDS Community Research Consortium
Mari Steeno, RN
(650) 364-6563

Center for Special Immunology - Irvine
Sandra Casserella, RN
(714) 753-0670

Davies Medical Center HIV Institute
Stephanie La Carrubba, RN
(415) 565-6524

ViRx, Inc. - Palm Springs
Val Crotty
(760) 864-6266

29. HIV Infection: rhIL-2

Title:

ACTG 328: A Phase II Study of Intermittent rhIL-2 by Intravenous or Subcutaneous Administration in Patients with HIV Infection on Highly Active Antiretroviral Therapy (HAART) or HAART Alone

Type of treatment:

Interleukin-2: immune modulator

Purpose:

To find out which method of taking rhIL-2 (by injection under the skin or by infusion into a vein) in combination with highly active antiretroviral therapy works best to increase the number of CD4+ cells (T-cells) in the blood.

About the study:

All patients will receive highly active antiretroviral therapy, consisting of two nucleoside analogs and the protease inhibitor, indinavir (Crixivan), for 12 weeks. After ten weeks of antiretroviral therapy, patients will have a test to find out how much HIV virus is in their blood. Patients with more than 5,000 copies/mL of HIV virus in their blood will not continue in the study. Patients with fewer than 5,000 copies/mL of HIV will be assigned by chance to continue to receive highly active antiretroviral therapy (HAART) by itself, or to add rhIL-2, taken either by injection under the skin or by infusion into a vein. rhIL-2 is given in "cycles", consisting of five days of daily therapy every two months. If patients who receive rhIL-2 by infusion experience a substantial increase in their CD4+ cells (T-cells), they will receive rhIL-2 by injection under the skin for the remainder of the study. Study visits are approximately once a month at the beginning of the study, and then every two months later on. The entire study lasts 21 months.

Required:

- CD4 cell (T-cell) range: between 50 and 300
- Viral load range: not applicable
- HIV positive
- At least 18 years old
- Must be able to start taking either AZT + 3TC, AZT + ddI, d4T + 3TC or d4T + ddI

Not allowed:

- Past or current AIDS-defining illnesses, except minimal Kaposi's sarcoma
- Any prior use of rhIL-2 or any protease inhibitors
- Use of corticosteroids, interferons, interleukins, thalidomide, GM-CSF, DNCB, thymopentin, losprinosine, Ampligen or Imuthiol within four weeks of study entry
- Women who are pregnant or breastfeeding
- Any cancers requiring treatment. Radiation therapy is allowed
- Active substance abuse that could interfere with the study

Location:

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

AIDS Community Research Consortium
Debbie Slamowitz, RN
(650) 364-6563

UCSF AIDS Program at SFGH/ACTU
Kathy Dybeck, RN
(415) 476-9296 ext. 353

LAC-USC Medical Center
Luis Mendez, RN
(213) 343-8288

Harbor-UCLA Medical Center
Sandra Houston, LVN
(310) 222-5291

Stanford University Medical Center
Sandra Valle, PA-C
(650) 723-8169

30. HIV Infection: Leukocyte Interleukin

Title:

Leukocyte Interleukin Injection (LI): A Pilot Phase I Study in HIV-1 Infected Subjects

Type of treatment:

Leukocyte Interleukin: immune modulator

Purpose:

To see if leukocyte interleukin is safe when injected in persons with HIV infection and to see if it has any effect on CD4 cell counts, viral load and other immune cell functions.

About the study:

This is a dose escalating study. This means that the first patients to enter the study will receive the low dose of leukocyte interleukin. After two weeks, the next group of patients will enter the study at the higher dose. Leukocyte interleukin is given by injection under the skin five times a week (Monday - Friday). Those in the low dose group will be injected once a day; those in the high dose will be injected twice a day. Patients will be taught how to give themselves injections. Study visits will occur every two weeks and the study lasts eight weeks.

Required:

- CD4 cell (T-cell) range: 500 or greater
- Viral load range: not applicable

- HIV positive
- At least 18 years old
- Must be on stable triple antireroviral therapy (two reverse transcriptase inhibitors and one protease inhibitor) for at least three months prior to study entry

Not allowed:

- Any active opportunistic infections
- Women who are pregnant or breastfeeding
- Active substance abuse
- Any changes in antiretroviral therapy within the last 90 days
- Any significant cardiac, liver or nervous system diseases
- Use of any immune modulators such as interleukins, interferons, steroids, chemotherapy within 12 weeks of study entry
- Unintended weight loss of more than 10% in the past six months
- Any vaccinations or flu shots within 90 days of study entry
- Any cancers including Kaposi's Sarcoma

Location:

AIDS Research Alliance
Corie Castro
(310) 358-2429

31. HIV Infection in Men: Nandrolone Decanoate, Exercise

Title:

Nandrolone Decanoate and Resistance Training for Augmenting Muscle Mass in Patients with HIV

Type of treatment:

Nandrolone Decanoate: anabolic steroid
Exercise:

Purpose:

To see if weight training combined with anabolic steroid treatment is more effective in gaining muscle mass than with an anabolic steroid alone.

About the study:

All patients will receive nandrolone decanoate and will be assigned by chance to train with weights or to not train with weights. Nandrolone is given by injection into a muscle once a week for 12 weeks. Those patients assigned to exercise will work out three times a week with a professional trainer and will travel to the USC facility, just east of downtown Los Angeles. After 12 weeks of nandrolone treatment, all patients will have the opportunity to receive instructions about weight training and be followed for an additional 12 weeks. The study lasts 24 weeks.

Required:

- CD4 cell (T-cell) range: between 50 and 400
- Viral load range: less than 30,000 copies/mL
- HIV positive male patients only
- At least 18 years old
- Less than 5% total weight loss
- Patients with less than 200 T-cells must be taking PCP prophylaxis
- Patients must be receiving at least 2 antiretroviral treatments, one of which must be either 3TC or a protease inhibitor
- Willingness to work out three times a week and travel to the USC facility

Not allowed:

- Female patients
- Prior diagnosis of wasting **OR** more than 5% weight loss in the preceding year
- No active AIDS defining infections or cancers
- Currently using Megace
- Patients with cardiac disease or diabetes requiring treatment
- Chronic active hepatitis B or C
- Use of immunomodulators (interferons, interleukins, thalidomide, corticosteroids)
- Previous use of anabolic steroids or human growth factor
- Prostate enlargement

Location:

LAC-USC Medical Center
Connie Olson, RN
(213) 343-8279

32. HIV Infection: DMP-266, Indinavir, AZT, 3TC

Title:

DMP-266-006: A 24 Week Phase II, Multicenter, Randomized, Open-Label Study to Compare Antiretroviral Activity and Tolerability of Three Different Combination Regimens (DMP-266 + Indinavir; DMP-266 + Zidovudine + Lamivudine; Indinavir + Zidovudine + Lamivudine) in HIV-Infected Patients

Type of treatment:

AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Indinavir: antiretroviral, protease inhibitor
DMP-266: antiretroviral, non-nucleoside reverse transcriptase inhibitor (NNRTI)
3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To compare the safety and effectiveness of the three combinations. To see how long it takes to develop resistance to DMP-266

About the study:

Patients are assigned by chance to one of three treatments: DMP-266 + indinavir; DMP-266 + AZT + 3TC or indinavir + AZT + 3TC. Patients will

know which treatment they are receiving. All medications are pills and taken by mouth. There are no placebos in this study. Study visits will be every four weeks and the study lasts for 24 weeks.

Required:

- CD4 cell (T-cell) range: at least 50
- Viral load range: at least 10,000 copies/mL
- HIV positive
- Between 13 and 60 years old
- Use of antiretrovirals must be discontinued at least two weeks prior to study entry

Not allowed:

- Women who are pregnant or breastfeeding
- Prior use of 3TC, DMP-266, any protease inhibitor or NNRTI (such as delavirdine, nevirapine)
- Use of any experimental drug within 30 days of study entry
- Currently being treated for any opportunistic infection or malignancy (cancer)
- Use of rifampin, rifabutin, fluconazole, ketoconazole, itraconazole, erythromycin, azithromycin, clarithromycin or greater than 1gram/day of Vitamin C throughout the study
- Active substance or alcohol abuse

Location:

ViRx, Inc.
Debbie Hildebrandt
(415) 353-5623

AIDS Healthcare Foundation
Edwin Graham, RN
(213) 913-3953

Kaiser San Francisco - HIV Research Unit
Joseph Thatcher, RN, MSN
(415) 202-2529

Pacific Oaks Research Group
Kai Gu, RN
(310) 360-8800

St. Luke Medical Group & Clinical Trials
Rebecca Gonzalez
(619) 235-4211

Center for Special Immunology - Irvine
Sandra Casserella, RN
(714) 753-0670

ViRx, Inc. - Palm Springs
Val Crotty
(760) 864-6266

33. HIV Infection: Indinavir, AZT, 3TC

Title:

Merck 060: Multiclinic Open Study to Evaluate the Ability of the Combination of Indinavir, Zidovudine and Lamivudine to Result in Sustained Supression of HIV-1 in Asymptomatic HIV-1 Seropositive Patients

Type of treatment:

AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Indinavir: antiretroviral, protease inhibitor

Purpose:

To see if the combination of indinavir, AZT and 3TC can result in undetectable levels of HIV in blood and tissue and to see what happens to HIV levels when antiretroviral therapy is discontinued.

About the study:

All patients will receive indinavir, AZT and 3TC. Patients who achieve HIV viral load levels below the limit of detection for 48 consecutive weeks will have tests done to see if HIV is present in their lymph nodes, spinal fluid and semen. A lymph node biopsy and spinal tap will be required. If these results are negative and the viral load of the blood remains undetectable for an additional 72 weeks, patients will discontinue antiretrovirals and continue to be followed for long term outcome. Study visits are every month and the study lasts approximately four years.

Required:

- CD4 cell (T-cell) range: more than 500
- Viral load range: more than 1,000 copies
- HIV positive
- At least 18 years old
- Must not have had any treatment for HIV infection

Not allowed:

- Past or current use of antiretrovirals, protease inhibitors or immunomodulators
- Past or current AIDS-defining conditions

Location:

UCSF AIDS Program at SFGH/ICTG
Doug Raggett, RN
(415) 476-9296, ext. 312

LAC-USC Medical Center
Irene Teran, RN
(213) 343-8285

AIDS Community Research Consortium
Mari Steeno, RN
(650) 364-6563

34. HIV Infection: Remune, Indinavir, AZT, 3TC

Title:

IRC 816: A Phase II Study to Evaluate the Combination of Remune (HIV-1 Immunogen) and Triple Antiviral Drug Therapy on HIV-1 Specific Immunogenicity in HIV-1 Infected Subjects with CD4 Counts of More than 400

Type of treatment:

AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Remune: immune modulator
Indinavir: antiretroviral, protease inhibitor

Purpose:

To see if Remune, in combination with AZT, 3TC and indinavir OR alone, is safe and effective in fighting HIV.

About the study:

Patients are assigned by chance to receive Remune + indinavir + AZT + 3TC OR Remune placebo (called IFA) + indinavir + AZT + 3TC. Neither patients nor their doctors will know which they are receiving until the study ends. Indinavir, AZT and 3TC are pills and taken by mouth. Remune and its placebo are given by injection into a muscle at weeks 4, 16 and 28. All patients will receive triple drug therapy (indinavir, AZT, 3TC) for four weeks before starting Remune. Study visits are once a month and the study lasts 32 weeks.

Required:

- CD4 cell (T-cell) range: more than 400
- Viral load range: not applicable
- HIV positive
- At least 16 years old

Not allowed:

- Current opportunistic infections except thrush and hairy leukoplakia
- Women who are pregnant or breastfeeding
- Any cancer requiring treatment other than basal cell or cervical
- Active substance abuse
- Previous use of any protease inhibitor or 3TC
- Previous participation in a Remune study

Location:

UC Irvine Medical Center
Josephine Mosquara
(714) 456-7612

UC Davis Medical Center
Michael Peterson
(916) 734-8282

35. HIV Infection: 141W94, Invirase, Nelfinavir, Indinavir

Title:

PROA2001: A Phase I/II Screening Trial to Identify Potential Partner Compounds to Use in Combination with 141W94

Type of treatment:

Indinavir: antiretroviral, protease inhibitor
Invirase: antiretroviral, protease inhibitor
Nelfinavir: antiretroviral, protease inhibitor
141W94: antiretroviral, protease inhibitor
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see if 141W94 is safe and to see if it is absorbed into the blood stream. To see if 141W94 has the ability to fight HIV when used in combination with other protease inhibitors.

About the study:

Patients are assigned by chance to receive 141W94 with either Soft Gel Invirase, nelfinavir or indinavir, or to receive 141W94 by itself. After three weeks, those patients assigned to take 141W94 by itself will also take AZT and 3TC. All medications are pills and taken by mouth. Patients will know which medications they are taking. Study visits are once a week for the first month, then once a month. At week two, there will be an all day study visit to perform multiple blood draws. The study lasts 6 months with a possible extension.

Required:

- CD4 cell (T-cell) range: At least 200
- Viral load range: more than 10,000 copies/mL
- HIV positive
- At least 18 years old

Not allowed:

- All antiretrovirals must be discontinued for two weeks prior to study entry
- Prior use of any protease inhibitors or immunomodulators
- Any radiation or chemotherapy within four weeks of study entry
- Concurrent use of clarithromycin, dapsone, rifampin, itraconazole, ketoconazole or rifabutin

Location:

UCSD Treatment Center
Anne French, RN
(619) 543-8080 ext. 238

ViRx, Inc.
Debbie Hildebrandt
(415) 353-5623

36. HIV Infection: Lobucavir

Title:

A1459-015: Multiple Dose, Safety, Pharmacokinetic and Antiviral Activity Study of Oral Lobucavir in HIV-Infected Subjects

Type of treatment:

Lobucavir: antiviral

Purpose:

To see how different doses of lobucavir are processed by the body.

About the study:

Patients are assigned by chance to take lobucavir once a day or twice a day. Lobucavir is a pill and taken by mouth. Patients will know which dose they are taking. Study visits are at one week, two weeks and four weeks. There are three pharmacokinetic days during the study. During pharmacokinetic study days, patients will be required to stay at the hospital for about 13 hours. The study lasts six weeks. Patients will be paid for completing the study.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: at least 10,000 copies/mL
- At least 18 years old
- Patients must be antiretroviral naive

Not allowed:

- Past or current use of any antiretroviral or protease inhibitors
- Any current opportunistic infection requiring therapy
- Diarrhea that has not responded to treatment

Location:

UCSD Treatment Center
Anne French, RN
(619) 543-8080 ext. 238

Harbor-UCLA Medical Center
Sandra Houston, LVN
(310) 222-5291

37. HIV Infection: Indinavir, ddI, d4T

Title:

AI455-056: A Randomized, Blinded Study of the Antiretroviral Effect and Safety of ddI, ddI + d4T, or ddI + d4T + Indinavir in Treatment-Naive HIV-Infected Subjects

Type of treatment:

ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Indinavir: antiretroviral, protease inhibitor

Purpose:

To observe the antiviral activity of each of these three treatments.

About the study:

Patients are assigned by chance to receive ddI OR ddI plus d4T OR to receive ddI plus d4T plus indinavir. Patients assigned to take ddI will also take two placebos. Patients assigned to ddI plus d4T will take one placebo. Those assigned to take ddI plus d4T plus indinavir will take no placebos. If after 12 weeks patients don't respond by a drop in viral load to below 500, then all patients will receive ddI, d4T and indinavir. All medications are pills and taken by mouth. Study visits are every four weeks for the first 24 weeks, then every 8 weeks. The study lasts at least 48 weeks.

Required:

- CD4 cell (T-cell) range: at least 100
- Viral load range: between 5,000 and 10,000 copies/mL
- HIV positive
- At least 18 years old
- Any previous use of AZT, ddC or 3TC must have been for less than four weeks

Not allowed:

- Prior use of any antiretrovirals other then AZT, ddC or 3TC for more than four weeks
- Prior use of any protease inhibitors or immunomodulators, such as interferons or interleukins
- Any current opportunistic infections

Location:

UCSF AIDS Program at SFGH/ICTG
Anna Smith, RN
(415) 476-9296, ext. 313

Shared Medical Research Foundation
Vicky Ramirez
(818) 345-2172

38. HIV Infection: 141W94, AZT, 3TC

Title:

PROAB3001: A Phase III Trial to Evaluate the Safety and Antiviral Efficacy of 141W94 in Combination with AZT and 3TC versus AZT and 3TC Alone in Patients with HIV Infection

Type of treatment:

1592U89: antiretroviral
141W94: antiretroviral, protease inhibitor
3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see if the new protease inhibitor, 141W94, is safe and effective in treating HIV disease when used with AZT and 3TC.

About the study:

All patients will take AZT and 3TC. Patients are assigned by chance to receive 141W94 or placebo. Neither patients nor their doctors will know

which they are receiving until the study ends. All medications are pills and taken by mouth twice a day. After week 16, patients who have two consecutive viral loads of more then 5,000 copies will be allowed to switch to quadruple therapy consisting of AZT, 3TC, 141W94, and 1592U89, an experimental reverse transcriptase inhibitor. Patients will be on study medication for 48 weeks.

Required:

- CD4 cell (T-cell) range: at least 200
- Viral load range: at least 10,000 copies/mL
- HIV positive

Not allowed:

- Any past or current AIDS-defining opportunistic infection
- Prior use of any protease inhibitors
- Use of more than four weeks of any antiretroviral medications

Location:

Pacific Oaks Research Group
Jamie Vitale
(310) 360-8800

East Bay AIDS Center
Nancy Orcutt, RN, MS
(510) 204-1291

39. HIV Infection: CD4-zeta Gene Therapy, IL-2

Title:

A-9602: Pilot Study of Autologous CD4-zeta Gene-Modified T Cell Infusion With or Without IL-2 in Patients with HIV Infection

Type of treatment:

Interleukin-2: immune modulator
CD4-Zeta T Cells: gene therapy

Purpose:

To see if CD4-zeta gene therapy with or without interleukin 2 is safe and to determine its antiviral activity.

About the study:

Patients are assigned by chance to receive a single infusion of their own CD4 zeta-gene modified T cells or a single infusion plus five days of a continuous interleukin 2 infusion. Before infusion, patients will give blood samples from which T cells are removed. Two human genes, CD4 and zeta, which occur naturally in T cells, are combined to produce the CD4-zeta gene. The CD4-zeta gene is added to the patient's T cells. The modified T cells are then given to the patient as an infusion into a vein. Patients will be monitored for 24 hours in the hospital after their T cell infusion. For patients assigned to receive five days of continuous IL-2 infusion, two IV lines will be required, one for the CD4-zeta gene T cells and one for the IL-2 infusion. Patients will be monitored for eight weeks follwing the infusion. Some study sites may pay patients for their participation.

Required:

- CD4 cell (T-cell) range: at least 50
- Viral load range: between 1,000 and 50,000 copies/mL
- HIV positive
- Patients must be on stable (no changes) antiretroviral therapy for at least eight weeks prior to study entry and continue this therapy for the duration of the study

Not allowed:

- Viral load of more than 10,000 copies if the CD4 count is between 50 and 199

Location:

ViRx, Inc.
Debbie Hildebrandt
(415) 353-5623

UCSF AIDS Program at SFGH/ICTG
Dorie Heeren, RN
(415) 476-9296, ext. 305

AIDS Community Research Consortium
Sharon O'Leary, RN
(650) 364-6563

40. HIV Infection: CI-1012

Title:

1012-005: A Phase I, Multiple Dose, Tolerance and Pharmacokinetic Trial of CI-1012

Type of treatment:

CI-1012: zinc finger inhibitor

Purpose:

To see if CI-1012 is safe and well-tolerated in patients who are HIV infected and have no symptoms. To see how CI-1012 is processed by the body.

About the study:

This is a dose-escalation study. This means that the first patients to enroll on the study will receive the lowest dose of CI-1012. If no bad side effects are observed, the next group of patients will receive a higher dose and so forth until the highest dose is found that does not cause bad side effects or the highest dose researchers plan to study has been given. All patients will receive CI-1012; there are no placebos in this study. CI-1012 is a pill and taken by mouth. There are 11 study visits in two and a half weeks and two of those study visits are all day visits. The study lasts four weeks.

Required:

- CD4 cell (T-cell) range: at least 200
- Viral load range: at least 10,000 copies/mL
- HIV positive
- Between 18 and 60 years old

Not allowed:

- Use of any antiretroviral therapy for at least three weeks prior to study entry
- Current AIDS-defining opportunistic infections except KS of the skin

Location:

ViRx, Inc.
Debbie Hildebrandt
(415) 353-5623

ViRx, Inc. - Palm Springs
Hugh Vance, PhD
(760) 864-6266

41. HIV Infection: 1592U89, Indinavir, DMP-266

Title:

ACTG 368: A Randomized, Phase II, Placebo-Controlled Trial of 1592U89 in Combination with Open-Label Indinavir Sulfate (IDV) and DMP-266 in HIV-Infected Subjects with Nucleoside Analog Experience: A Rollover Study for ACTG 320

Type of treatment:

DMP-266: antiretroviral, non-nucleoside reverse transcriptase inhibitor (NNRTI)
Indinavir: antiretroviral, protease inhibitor
1592U89: antiretroviral

Purpose:

To see if potent new drugs are safe and effective in reducing HIV-1 RNA viral load in HIV-infected patients who have taken nucleoside analogs (AZT, ddI, ddC, d4T, 3TC) before but have never taken non nucleoside reverse transcriptase inhibitors (NNRTI), such as delavirdine or nevirapine.

About the study:

Patients are assigned by chance to one of four treatment groups. All groups will take indinavir and DMP 266 but at two different doses. Patients will also be assigned to take 1592U89 or placebo. Neither patients nor their doctors will know whether they are receiving 1592U89 or placebo until the study ends. Study visits are once a month and the study lasts 72 weeks.

Required:

- CD4 cell (T-cell) range: 200 or less
- Viral load range: not applicable
- HIV positive
- At least 18 years old
- Patients must have participated in ACTG 320 and were assigned to take double-nucleoside combination therapy **OR**
- Patients who did not participate in ACTG 320 may enroll if they have at least 3 months of therapy with AZT (or d4T) plus 3TC and are receiving AZT (or d4T) plus 3TC at the time of study entry

Not allowed:

FOR ACTG 320 PATIENTS:

- Patients who received indinavir at any time during the course of ACTG 320

FOR NON-ACTG 320 PATIENTS:

- Acute therapy for an infection or other illness within 14 days of study entry
- Unexplained fever (>101.3F) for any 7 days within 30 days prior to study entry
- Chronic diarrhea, defined as more than three liquid stools per day, persisting for 15 days within 30 days prior to study entry
- Any cancers requiring chemotherapy. Minimal KS of the skin is allowed if it does not require chemotherapy
- Acute hepatitis within 30 days prior to study entry
- Prior use of any protease inhibitors or NNRTI therapy, such as delavirdine or nevirapine
- Use of erythropoietin. G-CSF, GM-CSF, interferons, interleukins, HIV vaccines or any investigational drug within 30 days of study entry
- Use of rifampin or rifabutin within 14 days of study entry or at anytime throughout the study
- Women who are pregnant or breastfeeding

Location:

Stanford University Medical Center
Jane Norris, PA
(650 723-2805

UCSF AIDS Program at SFGH/ACTU
Kathy Dybeck, RN
(415) 476-9296 ext. 353

Kaiser San Francisco - HIV Research Unit
Susan Kirk, RN
(415) 202-3484

42. HIV Infection: HIV-IT

Title:

CS-GT003: A Phase II, Randomized, Double-Blind, Placebo-Controlled Study of Combination Drug Antiretroviral Therapy to Include a Reverse Transcriptase Inhibitor and a Protease Inhibitor Plus HIV-IT or Placebo in HIV Patients with CD4 Counts of at least 100 and HIV RNA at least 1,000 but not more than 10,000

Type of treatment:

HIV-IT: immune modulator, gene therapy

Purpose:

To see if HIV-IT (gene therapy) is safe and effective in treating HIV disease when given with combination antiretroviral therapy.

About the study:

Patients are assigned by chance to receive HIV-IT or placebo. Neither

patients nor their doctors will know which they are receiving until the study ends. HIV-IT and its placebo are given by injection into a muscle every two weeks. Study visits are every two weeks and the study lasts for 29 weeks. Some study sites may pay participants for completing the study.

Required:

- CD4 cell (T-cell) range: at least 100
- Viral load range: between 1,000 and 10,000 copies/mL
- HIV positive
- Between 18 and 65 years old
- Patients must be on combination antiretroviral therapy with at least one reverse transcriptase inhibitor and a protease inhibitor for at least two months prior to study entry

Not allowed:

- Past use of any immune modulators such as interferons, interleukins, vaccines, T-cell infusions and gene therapy
- Women who are pregnant or breastfeeding
- Use of any investigational drug, corticosteroids, radiation treatment or chemotherapy within 30 days of study entry

Location:

Marin County Specialty Clinic
Alison Clayton
(415) 499-6796

California Clinical Trials Medical Group
Clinic Staff
(888) 228-7425

AIDS Community Research Consortium
Sharon O'Leary, RN
(650) 364-6563

43. HIV Infection: Nevirapine, Nelfinavir, d4T

Title:

1100.1224: An Investigation of the Potential Pharmacokinetic Interaction Between Nevirapine (Viramune) and Nelfinavir (Viracept) and the Efficacy of this Combination Therapy in HIV-1 Infected Adults Treated with Stavudine (d4T) (Zerit)

Type of treatment:

Nelfinavir: antiretroviral, protease inhibitor
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Nevirapine: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI

Purpose:

To see how nevirapine, nelfinavir and d4T are processed by the body and to see how they interact with each other. To see if the combination of these three drugs is safe and effective in treating HIV disease.

About the study:

Patients starting this study will take d4T and nelfinavir for one week. After one week, patients will take nelfinavir, nevirapine and d4T for the remainder of the study. All medications are pills and taken by mouth. All patients will receive active medication, there are no placebos in this study. Study visits are once a week for the first six weeks, then once a month until week 30, then once every two months until the end of the study. Two overnight hospital stays are required at week 1 and week 6. The study lasts 65 weeks.

Required:

- CD4 cell (T-cell) range: at least 100
- Viral load range: at least 5,000 copies/mL
- HIV positive
- Between 18 and 65 years old
- Six months or less of d4T use

Not allowed:

- Prior use of any non-nucleoside reverse transcriptase inhibitors (NNRTIs) such as nevirapine, delavirdine, DMP-266 or loviride
- Prior use of any protease inhibitors
- Women who are pregnant or breastfeeding
- Use of d4T for more than six months
- Use of any investigational drug within 30 days of study entry
- Current active infections
- Use of erythromycin, clarithromycin, azithromycin, ketoconazole, fluconazole, intraconazole, rifabutin or rifampin within 14 days of study entry
- Patients who are heavy smokers (>20 cigarettes per day)

Location:

HIVCare, Saint Francis Memorial Hospital
Sal Iacopelli
(415) 353-6298

44. HIV Infection: Adefovir Dipivoxil, Nelfinavir, Saquinavir, AZT, 3TC, d4T

Title:

GS-97-417: A Phase II, Stratified, Randomized, Double Blind, Multi-Center Study of the Safety and Efficacy of Adefovir Dipivoxil (ADF) at Two Dose Levels in Triple Combination Therapies with Protease Inhibitors (PI) and Nuceloside Reverse Transcriptase Inhibitors (RTI) for the Treatment of HIV-Infected Patients with CD4 Cell Counts of Equal to or Greater than 100 and HIV-1 RNA Copy Numbers of Equal to or Greater than 5,000 copies/mL and Prior RTI Therapy but no Prior PI Therapy

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Each study listing includes:

- Name of study
- Purpose of study
- What the study involves
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- Whether the study pays participants
- Names and phone numbers of people to call if you want to join the study or ask questions.

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On the reverse side of this page is a brief questionnaire that asks for information about your current health and your medical history. This information is matched with all of the clinical trials in our computer database. Within two working days of receiving your completed questionnaire we will send you a **Trials Search** report.

It is important to answer each of the questions completely. If you have problems filling out the questionnaire, call our toll-free number for assistance. Your doctor or other health care provider can also help. A nurse or medical office staff person may be able to answer these questions on the telephone.

Trials Search *is a service provided by the Community Consortium, an association of Bay Area HIV health care providers. The Community Consortium is affiliated with the UCSF AIDS Program at San Francisco General Hospital.*
Trials Search *was originally developed by Jay Seward and Brian Christianson of the Institute for HIV Research and Treatment at Davies Medical Center in San Francisco.*

Contact Information:

All information is mailed to you in a plain envelope. In some cases we may need to call you to clarify information on your questionnaire. Your name and other personal information is held in the strictest confidence.

NAME _____

ADDRESS _____

CITY _____ STATE _____ ZIP _____

TELEPHONE _____ FAX (for response by Fax) _____

May we leave a message? ❒ yes ❒ no Is this a private Fax? ❒ yes ❒ no

May we contact you by mail in the future? ❒ yes ❒ no

How did you hear about **Trials Search**? ❒ Doctor's Office/Clinic ❒ Friend ❒ Ad ❒ Community Agency ❒ Other _____

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Trials Search/Community Consortium
3180 18th Street, #201, San Francisco, CA 94110
Toll-free: **1-(800) 492-5777** Phone: **(415) 476-5777** Fax: **(415) 502-8686**
E-mail: **tsearch@sfaids.ucsf.edu** Internet: **http://hivinsite.ucsf.edu/tsearch** TSI1097

Trials Search Questionnaire

Date Completed: ____/____/____ (mo/day/year) Date of Birth: ____/____/____ (mo/day/year)

Sex: ❒ Male ❒ Female First initial & last initial: _____ _____

Medical History:

Absolute CD4 Cell Count (T-helper cells): _____ HIV RNA Viral Load: _____

Check the first column **(Past)** for each condition you have had in the past, but no longer have.
Check the second column **(Current)** for each medical condition that you currently have.

Past	Current		Past	Current	
○	❒	Anal or Genital Warts	○	❒	Lymphoma - Hodgkin's
○	❒	Candidiasis - Esophageal (throat)	○	❒	Lymphoma - Non-Hodgkin's
○	❒	Candidiasis - Oral (thrush)	○	❒	MAC or MAI (Mycobacterium avium Complex)
○	❒	Candidiasis - Vaginal (recurrent yeast infection)	○	❒	Molluscum Contagiosum
○	❒	Cryptococcal Meningitis	○	❒	Pancreatitis
○	❒	Cryptosporidiosis	○	❒	PCP (Pneumocystis carinii Pneumonia)
○	❒	CMV (Cytomegalovirus) - Retinitis	○	❒	Peripheral Neuropathy
○	❒	CMV - Gastrointestinal	○	❒	PID (Pelvic Inflammatory Disease)
○	❒	Dementia	○	❒	PML (Progressive multifocal leukoencephalopathy)
○	❒	Diarrhea - HIV Related	○	❒	Sinusitis
○	❒	Hairy Leukoplakia	○	❒	Syphilis
○	❒	Herpes Simplex Virus	○	❒	Toxoplasmosis
○	❒	Herpes Zoster Virus (shingles)	○	❒	Tuberculosis (TB)
○	❒	ITP (Immune Thrombocytopenia Purpura)	○	❒	Wasting Syndrome (unintended weight loss > 10%)
○	❒	KS (Kaposi's sarcoma) - skin and mouth	○	❒	Other:
○	❒	KS (Kaposi's sarcoma) - internal organs			

HIV Medication History:

Check the first column **(Past)** for each medication you have taken in the past, but no longer take.
Check the second column **(Current)** for each medication that you currently take.

Past	Current		Past	Current		Past	Current	
○	❒	3TC (Epivir)	○	❒	ddI (Didanosine, Videx)	○	❒	Mycelex (Clotrimazole)
○	❒	Acyclovir (Zovirax)	○	❒	Delavirdine (Rescriptor, U-90)	○	❒	NAC (Mucomyst)
○	❒	Alpha-Interferon (Wellferon, Roferon-A, Intron-A)	○	❒	Diclazuril	○	❒	Nelfinavir (Viracept)
			○	❒	DNCB	○	❒	Nevirapine (Viramune)
○	❒	Amikacin (Amikin)	○	❒	EPO (Epogen, Procrit)	○	❒	Nystatin (Mycostatin)
○	❒	Amphotericin-B (Fungizone, Ablacet)	○	❒	Ethambutol (Myambutol)	○	❒	Aero Pentamidine (Nebupent)
			○	❒	Fluconazole (Diflucan)	○	❒	IV Pentamidine
○	❒	Atovaquone (Mepron)	○	❒	Foscarnet (Foscavir)	○	❒	Pyrimethamine (Daraprim)
○	❒	Azithromycin (Zithromax)	○	❒	Ganciclovir - IV (Cytovene)	○	❒	Rifabutin (Mycobutin)
○	❒	AZT (Retrovir, Zidovudine)	○	❒	Ganciclovir - oral	○	❒	Rifampin (Rifadin, Rimactane)
○	❒	Bactrim/Septra (TMP-SMX)	○	❒	Ganciclovir - implants	○	❒	Ritonavir (Norvir)
○	❒	Chemotherapy - local	○	❒	G-CSF (Neupogen, Filgastrim)	○	❒	Sparfloxacin
○	❒	Chemotherapy - systemic	○	❒	Indinavir (Crixivan)	○	❒	Testosterone
○	❒	Clarithromycin (Biaxin)	○	❒	INH (Isoniazid)	○	❒	Thalidomide
○	❒	Clindamycin (Cleocin)	○	❒	Invirase (Saquinavir)	○	❒	HIV Vaccine
○	❒	Clofazimine (Lamprene)	○	❒	Itraconazole (Sporanox)	○	❒	Other Antifungal
○	❒	d4T (Stavudine)	○	❒	Ketoconazole (Nizoral)	○	❒	Other Antiretroviral
○	❒	Dapsone	○	❒	Marinol (Dronabinol)	○	❒	Other Immune Modulator
○	❒	ddC (Zalcitabine, HIVID)	○	❒	Megace (Megesterol acetate)	○	❒	Other:

Have Questions? Need Help? Call (415) 476-5777 (local) or 1-800-492-5777 (toll free).

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Nelfinavir: antiretroviral, protease inhibitor
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Invirase: antiretroviral, protease inhibitor
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Adefovir dipivoxil: antiretroviral, reverse transcriptase inhibitor, nucleotide analog

Purpose:

To see if two doses of adefovir dipivoxil (also called bis-POM PMEA) are safe and effective in treating HIV disease when combined with protease inhibitor (nelfinavir, saquinavir) and nuceloside RTI therapy (AZT, 3TC, d4T).

About the study:

Patients are assigned by chance to one of three groups. The first group will take adefovir dipivoxil, nelfinavir (also called Viracept), and saquinavir soft gel capsules. The second group will take adefovir dipivoxil, nelfinavir and either AZT, 3TC or d4T. The third group will take adefovir dipivoxil, saquinavir soft gel capsules and either AZT, 3TC or d4T. Neither patients nor their doctors will know which medications they are taking until the study ends. All medications are pills and taken by mouth. There are two study visits during the first month, then a visit every two months. The study lasts one year

Required:

- CD4 cell (T-cell) range: at least 100
- Viral load range: at least 5,000 copies/mL
- HIV positive
- At least 16 years old
- Prior therapy for more than four weeks with any licensed nuceloside analog (AZT, ddI, ddC, d4T, 3TC)

Not allowed:

- Prior use of adefovir dipivoxil
- Prior use of any protease inhibitor
- Any new AIDS-defining event within one month of study entry
- Any immunizations within 30 days of study entry
- Antiretroviral vaccine therapy within 60 days of study entry
- Any active, serious infections requiring parenteral antibiotic therapy
- Any treatment with corticosteroids, interleukins or intererons within four weeks of study entry or throughout the study
- Women who are pregnant or breastfeeding
- Any cancers other than KS or basal cell carcinoma of the skin
- Prior significant peripheral neuropathy
- Patients with chronic nausea and/or vomiting
- Active alcohol or substance abuse

Location:

Kraus Medical Partners
Douglas Bowden
(213) 930-2324

AIDS Healthcare Foundation
Matt Moran, RN
(213) 913-3953

Davies Medical Center HIV Institute
Stephanie La Carrubba, RN
(415) 565-6524

45. HIV Infection: 1592U89, AZT, 3TC

Title:

CNAA/B3003: A Randomized, Double-Blind, Parallel-Group, Multicenter Trial to Evaluate the Safety and Efficacy of 1592U89 in Combination with Lamivudine (3TC) and Zidovudine (ZDV) Versus 3TC/ZDV in HIV-1 Infected Antiretroviral Therapy Naive Subjects with CD4+ Counts of Equal to or Greater than 100 cells/mm^3

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
1592U89: antiretroviral
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To compare the antiviral activity and viral load response of 1592U89 plus 3TC plus AZT versus AZT plus 3TC. To see if these combinations are safe and well-tolerated.

About the study:

All patients will take AZT and 3TC and 1592U89 . There are no placebos in this study. All medications are pills and taken by mouth. Study visits are every two weeks for the first month, then every four weeks for at least 48 weeks. The study lasts about one year. After week 16, patients who were in enrolled when there was a placebo phase of the study may switch over to open-label (active) 1592U89.

Required:

- CD4 cell (T-cell) range: at least 100
- Viral load range: not applicable
- HIV positive
- At least 13 years old

Not allowed:

- Prior use of any antiretroviral therapy
- Any pancreatitis or hepatitis within the past six months
- Active alcohol or substance use
- Women who are pregnant or breastfeeding
- Radiation or chemotherapy (or the need for such during the study) within 30 days of study entry. Local treatment for KS is allowed.
- Treatment with an HIV vaccine within three months prior to study entry
- Treatment with immunomodulators (such as corticosteroids, interleukins, interferons) within 30 days of study entry

- Active opportuniistic infections
- Patients receiving foscarnet therapy

Location:

East Bay AIDS Center
Nancy Orcutt, RN, MS
(510) 204-1291

Kraus Medical Partners
Stanka Derzic
(213) 930-2324

46. HIV Infection: AZT, 3TC, AZT/3TC, Protease Inhibitor

Title:

NZTA4001: A Randomized, Multicenter Study of Epivir 150mg BID, Retrovir 200mg TID and a Protease Inhibitor versus 3TC 150mg/ZDV 300mg Fixed Dose Tablet Given BID with a Protease Inhibitor in HIV-Infected Patients

Type of treatment:

AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
AZT/3TC Fixed Dose: antiretroviral, nucleoside analog

Purpose:

To see if a fixed dose tablet of 3TC and AZT (called combivir) combined with a protease inhibitor is as good as AZT plus 3TC plus a protease inhibitor taken separately. To see if it is easier for patients to take their medications when AZT and 3TC are combined.

About the study:

Patients are assigned by chance to continue AZT plus 3TC plus a protease inhibitor or to receive fixed dose tablets of AZT/3TC plus a protease inhibitor. Patients will know which forms of AZT and 3TC they are taking. Study visits are once a month and the study lasts 16 weeks. Patients will be allowed to continue to take the AZT/3TC fixed dose after 16 weeks if they choose. AZT, 3TC and clinic visits will be paid for by the study.

Required:

- CD4 cell (T-cell) range: at least 300
- Viral load range: less than 10,000 copies/mL
- HIV positive
- At least 18 years old
- Must be on AZT, 3TC and a protease inhibitor for at least ten weeks immediately prior to start of study

Not allowed:

- Any past or current AIDS-defining opportunistic infections

Location:

UC Davis Medical Center
Bill Lippert, MBA
(916) 734-8475

Pacific Oaks Research Group
Jamie Vitale
(310) 360-8800

Tower Infectious Diseases
Tim Jordan, RN
(310) 358-2300 ext. 114

47. HIV Infection: DMP 266, Indinavir

Title:

DMP 266-020: A Phase III, Double-Blind, Placebo-Controlled, Multicenter Study to Determine the Effectiveness and Tolerability of the Combination of DMP 266 and Indinavir Versus Indinavir in HIV-Infected Patients Receiving Nucleoside Analogue (NRTI) Therapy

Type of treatment:

DMP-266: antiretroviral, non-nucleoside reverse transcriptase inhibitor (NNRTI)
Indinavir: antiretroviral, protease inhibitor

Purpose:

To study the effect of DMP 266 with indinavir versus indinavir alone in reducing viral load in HIV-infected patients. To see which of the two treatments is better tolerated.

About the study:

All patients will receive indinavir and will be assigned by chance to take DMP 266 or placebo with their nucleoside analogue (NRTI) therapy. Patients not currently taking nucleoside analogue therapy must start either one or two nucleoside analogues on Day 0. Neither patients nor their doctors will know which they are receiving until the study ends. There are three screening visits, then study visits are once a month. The study lasts six months. After six months, all patients will be given the option to continue on open-label DMP 266. Some study sites may pay participants for completing the study.

Required:

- CD4 cell (T-cell) range: at least 50
- Viral load range: at least 10,000 copies/mL
- HIV positive
- Between 13 and 60 years old
- Patients must have had at least eight weeks of nucleoside analogue therapy within 12 weeks of study entry. Any combination of therapy is acceptable except AZT plus d4T

Not allowed:

- Prior use of DMP 266, any protease inhibitors or any NNRTI, such as nevirapine or delavirdine
- Concomitant treatment with the combination of AZT and d4T
- Use of any investigational drug within 30 days of study entry
- Concomitant use of rifampin, terfenadine, astemizole, cisapride, triazolam and midazolam
- Acute hepatitis
- Uncontrolled diarrhea or vomiting lasting for more than four days within six weeks of study entry
- Active alcohol or substance use

Location:

Marin County Specialty Clinic
Alison Clayton
(415) 499-6796

California Clinical Trials Medical Group
Clinic Staff
(888) 228-7425

LAC-USC Medical Center
Frances Canchola, RN
(213) 343-8281

Kaiser San Francisco - HIV Research Unit
Joseph Thatcher, RN, MSN
(415) 202-2529

48. HIV Infection: Adefovir Dipivoxil, Indinavir, AZT, 3TC, d4T

Title:

GS-96-411: A Phase II, Stratified, Randomized, Open-Label, Multicenter Study of the Safety and Efficacy of Adefovir Dipivoxil and Indinavir in Combination With Zidovudine, Lamivudine or Stavudine for the Treatment of Therapy-Naive HIV-Infected Patients with CD4 Cell Counts of 100 or More and HIV-1 RNA Copy Number of 5,000 Copies/mL or More

Type of treatment:

AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Indinavir: antiretroviral, protease inhibitor
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Adefovir dipivoxil: antiretroviral, reverse transcriptase inhibitor, nucleotide analog

Purpose:

To see if adefovir dipivoxil (also called bis-POM PMEA) is safe and well tolerated when given in combination with other anti-HIV drugs.

About the study:

Patients are assigned by chance to be in one of five treatment groups The groups are: adefovir dipivoxil plus indinavir plus AZT plus 3TC; adefovir dipivoxil plus indinavir plus AZT; adefovir dipivoxil plus indinavir plus 3TC; adefovir dipivoxil plus indinavir plus d4T; or indinavir plus AZT plus 3TC. All patients will know which medications they are taking. All medications are pills and taken by mouth. Study visits are once a month and the study lasts one year.

Required:

- CD4 cell (T-cell) range: at least 100
- Viral load range: at least 5,000 copies/mL
- HIV positive
- At least 18 years old

Not allowed:

- More than four weeks treatment with AZT, ddI, ddC, 3TC or d4T
- Prior use of any protease inhibitor
- Women who are pregnant or breastfeeding

Location:

AIDS Healthcare Foundation
Matt Moran, RN
(213) 913-3953

Davies Medical Center HIV Institute
Stephanie La Carrubba, RN
(415) 565-6524

49. HIV Infection: G-CSF (Filgrastim)

Title:

950121: A Multicenter, Randomized, Controlled, Open-Label Study to Determine the Efficacy of Filgrastim (r-metHuG-CSF) in the Reduction of Bacterial Infections in AIDS Patients

Type of treatment:

G-CSF: white blood cell stimulator

Purpose:

To see if Filgrastim (G-CSF) has the potential to reduce recurrent bacterial infections.

About the study:

Patients are assigned by chance to receive Filgrastim or to be observed. Those patients assigned to receive Filgrastim will have injections under the skin three times a week (Monday, Wednesday, Friday). Study visits are at day 14, day 28 and every 28 days thereafter up to 336 days. The study lasts about one year.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: not applicable
- HIV positive
- At least 13 years old
- Must have a documented diagnosis of AIDS
- Must enter the study within 30 days from the hospital discharge date for an NIAID/DAIDS defined bacterial infection **OR** from the resolution date of one of the following four infections:
  - Bacterial bloodstream only infection
  - Catheter related bacteremia/sepsis
  - Bacterial pneumonia
  - Bacterial endocarditis

Not allowed:

- Any cancer requiring chemotherapy within 12 weeks of study entry

- Use of ganciclovir or cidofovir within 14 days prior to study entry
- Use of any investigational drugs within 30 days of study entry
- Use of immunomodulators, such as interferons or interleukins, within 14 days prior to study entry
- Use of G-CSF or GM-CSF within 14 days prior to study entry
- Women who are pregnant or breastfeeding
- Known allergy to E. coli-derived products

Location:

Kaiser San Francisco - HIV Research Unit
Joseph Thatcher, RN, MSN
(415) 202-2529

Shared Medical Research Foundation
Karen Zunigar
(818) 345-2172

LAC-USC Medical Center
Luis Mendez, RN
(213) 343-8288

East Bay AIDS Center
Nancy Orcutt, RN, MS
(510) 204-1291

50. HIV Infection: VIRACEPT, AZT, 3TC

Title:

AG1343-603: An Open Label Study to Assess the Safety and Efficacy of BID Dosing of VIRACEPT + Zidovudine (ZDV) + Lamivudine (3TC) in HIV-Infected Treatment Naive Patients

Type of treatment:

Nelfinavir: antiretroviral, protease inhibitor
3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see if taking VIRACEPT, AZT and 3TC twice a day is safe and effective in reducing HIV-1 RNA viral load. To see what effect this combination has on CD4 cells (T-cells).

About the study:

All patients will take VIRACEPT, AZT and 3TC twice a day. All medications are pills and taken by mouth. There are no placebos in this study. Study visits are every two weeks for the first month, then once a month. The study lasts six months.

Required:

- CD4 cell (T-cell) range: at least 100
- Viral load range: at least 15,000 copies/mL
- HIV positive
- At least 13 years old

Not allowed:

- Active opportunistic infections
- Prior use of any antiretroviral medications
- Chronic diarrhea
- Any cancers requiring chemotherapy and/or any chemotherapy within 30 days prior to study entry
- Women who are pregnant or breastfeeding
- Active alcohol or substance abuse

Location:

Marin County Specialty Clinic
Alison Clayton
(415) 499-6796

51. HIV Infection: rgp 160 Vaccine

Title:

ACTG 946: A Phase I/II Double-Blind Controlled Trial to Determine the Safety and Immunogenicity of HIV-1 MN rgp 160 Immuno Vaccine Therapy in HIV-Infected Individuals with 200 - 400/mm^3 CD4 T Cells

Type of treatment:

Ritonavir: antiretroviral, protease inhibitor
ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
gp 160: vaccine
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see if MN rgp 160 is safe to take and to see what effect it has on immune function in HIV-infected patients.

About the study:

Patients will take ritonavir and increase the dose to 600 mg twice a day in two weeks. After two weeks, patients will add d4T and ddI. After nine weeks of triple combination therapy, patients are assigned by chance to receive rgp 160 vaccine or placebo. Injections will be given once a month for seven months.

Required:

- CD4 cell (T-cell) range: between 200 and 400
- HIV positive
- At least 18 years old
- Patients must have taken ritonavir for a full nine weeks and ddI plus d4T for at least seven weeks before entering the vaccine portion of the study

Not allowed:

- Previous use of any HIV vaccines
- Women who are pregnant or breastfeeding
- Chronic diarrhea, defined as four or more bowel movements per day persisting for four or more weeks within 30 days prior to study entry
- Use of immunomodulators, such as interferons, interleukins or corticosteroids within 90 days of study entry
- Any other vaccinations within 60 days of study entry
- Treatment for any AIDS-defining condition must be completed at least 90 days before study entry

- Severe peripheral neuropathy
- Chronic pancreatitis or acute pancreatitis within two years
- Use of 3TC or ddC within 90 days of study entry

Location:

Stanford University Medical Center
Sandra Valle, PA-C
(650) 723-8169

52. HIV Infection: Fortovase, Nelfinavir

Title:

NR15520B: A Randomized Phase IIIB Comparative Study to Evaluate Saquinavir Soft Gel Capsule (SGC) TID Regimen in Combination with Two NRTIs Versus Saquinavir Soft Gel Capsule (SGC) BID Regimen in Combination with Two NRTIs Versus Saquinavir Soft Gel Capsule (SGC) BID Plus Nelfinavir BID Plus an NRTI in HIV-1 Infected Patients

Type of treatment:

Fortovase: antiretroviral, protease inhibitor
Nelfinavir: antiretroviral, protease inhibitor

Purpose:

To see how effective treatment with saquinavir soft gel capsules (Fortovase) is at lowering HIV RNA load when used in three different dosages and drug combinations.

About the study:

Two different types of patients will be enrolled: antiretroviral experienced (persons with at least three months prior antiretroviral therapy) and antiretroviral naive (persons with no prior use of antiretrovirals). Patients are assigned by chance to one of three treatment groups. The first group will take saquinavir soft gel capsules (Fortovase) three times a day plus two new nuceloside analogs, such as AZT, 3TC, d4T, ddI, or ddC. The second group will take saquinavir soft gel capsules (Fortovase) twice a day plus two new nucleoside analogs. The third group will take saquinavir soft gel capsules (Fortovase) twice a day plus nelfinavir (Viracept) twice a day plus a new nucleoside analog. The antiretroviral(s) assigned will be "new" to the patient (no prior use). For experienced patients entering into groups 1 or 2 who have used four of the five antiretrovirals, the second assigned antiretroviral will be one used in the distant past. All patients will know which medications they are receiving. There are no placebos in this study. Study visits are once every two weeks for the first month; then once each month until 24 weeks, and then every two months until the end of the study at about one year. Some study sites may pay patients for their participation.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: at least 5,000 copies/mL
- HIV positive
- At least 16 years old
- For antiretroviral-experienced patients, more than three months of therapy with nucleoside analogs (AZT, 3TC, d4T, ddI, ddC)

Not allowed:

- More than two weeks of treatment with any protease inhibitors
- Prior use of any NNRTIs, such as nevirapine or delavirdine
- Women who are pregnant or breastfeeding

Location:

Marin County Specialty Clinic
Alison Clayton
(415) 499-6796

Kaiser San Francisco - HIV Research Unit
Barbara LeMaire, RN, MS
(415) 202-3486

Beer Medical Group
Heather Robertson
(213) 937-5151

Shared Medical Research Foundation
Karen Zunigar
(818) 345-2172

AIDS Healthcare Foundation
Matt Moran, RN
(213) 913-3953

East Bay AIDS Center
Nancy Orcutt, RN, MS
(510) 204-1291

St. Luke Medical Group & Clinical Trials
Rebecca Gonzalez
(619) 235-4211

Center for Special Immunology - Irvine
Sandra Casserella, RN
(714) 753-0670

53. HIV Infection: Fortovase, Nelfinavir (2)

Title:

Clinical, Virologic and Immunologic Effects of Four Drug/Double Protease Inhibitor Therapy with Saquinavir (Fortovase) Soft Gel Capsule and Nelfinavir (Viracept) in Combination with Reverse Transcriptase Inhibitors in the Treatment of HIV-1 in Antiretroviral Naive and in Indinavir Experienced Patients

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Nelfinavir: antiretroviral, protease inhibitor
Nevirapine: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI
Fortovase: antiretroviral, protease inhibitor
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see if a four drug therapy containing two protease inhibitors (saquinavir and nelfinavir) plus two reverse transcriptase inhibitors is safe and effective in reducing HIV RNA viral load in patients who have never used antiretrovirals and in patients who cannot tolerate or did not respond to indinavir (Crixivan).

About the study:

There are two separate subgroups in this study: A) antiretroviral naive patients (no prior use of antiretrovirals) and B) indinavir experienced patients. Patients in group A will be assigned to take saquinavir (Fortovase) plus nelfinavir plus d4T plus 3TC. Patients in group A will also be required to have two lymph node biopsies performed. Patients in group B will be further subdivided into two groups: those who have prior antiretroviral experience limited to AZT and/or 3TC; and those with a broader history of antiretroviral use which includes drugs other than or in addition to AZT and 3TC. Patients in the first subgroup will be assigned to take saquinavir Fortovase) plus nelfinavir plus d4T plus ddI. Those patients in the second subgroup will take saquinavir (Fortovase) plus nelfinavir plus adefovir (also called bis-POM PMEA) plus nevirapine. All patients in Group B will be required to spend two 8-hour days at the clinic for blood testing at weeks 4 and 28. After 24 weeks, those patients who have a sustained reduction in HIV RNA viral load below the limit of detection on at least three consecutive measurements will be assigned by chance to continue their current medications or to reduce the dose of their protease inhibitors. Those patients who have not reached undetectable levels but remain below their baseline level will not change their current medications for the remainder of the study. Study visits are once a month and the study lasts about one year.

Required:

- HIV positive
- At least 18 years old

GROUP A - antiretroviral naive

- CD4 cell (T-cell) range: patients with both less than 200 and more than 200 will be eligible
- Viral load range: at least 1,000 copies/mL

GROUP B - indinavir experienced

- CD4 cell (T-cell) range: more than 100
- Viral load range: at least 5,000 copies/mL
- Must have taken indinavir for at least 24 weeks and not have discontinued indinavir for a period greater than two months immediately prior to study entry
- Must have evidence of either indinavir intolerance or of an increasing HIV RNA viral load while on continued indinavir treatment

Not allowed:

- Women who are pregnant or breastfeeding
- Active infections requiring therapy within 14 days of study entry
- Any cancers requiring chemotherapy within one month of study entry and throughout the study
- Use of any investigational drugs, interferons, interleukins or vaccines within 30 days of study entry

GROUP A - antiretroviral naive

- Prior use of any antiretroviral therapy for more than seven days

GROUP B - indinavir experienced

- Prior use of any other protease inhibitors other than indinavir for more then seven days

Location:

Stanford University Medical Center
Sylvia Stoudt, RN
(650) 498-4040

54. HIV Infection: Fortovase, Nelfinavir, Ritonavir

Title:

NR15521B: A Phase IIIB Open-Label Trial Replacing Saquinavir Hard Gel Capsule (HGC) with Saquinavir Soft Gel Capsule (SGC) in Combination with Other Antiretroviral Drugs in Patients with HIV-1 Infection

Type of treatment:

Fortovase: antiretroviral, protease inhibitor

Purpose:

To see if the soft gel capsule formula of saquinavir (Fortovase) in combination with other antiretroviral medications is effective in lowering the amount of HIV RNA in the blood of patients currently taking the hard gel saquinavir (Invirase) capsule.

About the study:

Patients in this study will switch from hard gel capsules (Invirase) to soft gel capsules (Fortovase) of saquinavir. Patients will be assigned by chance to one of three groups. Patients in the first group will take soft gel saquinavir (Fortovase) with two new nucleoside analogs, such as AZT, ddI, ddC, d4T or 3TC. Patients in the second group will take soft gel saquinavir (Fortovase) plus nelfinavir plus d4T (or a new nucleoside

analog). Patients in the third group will take soft gel saquinavir (Fortovase) plus ritonavir plus d4T (or a new nucleoside analog). Patients will know which study drugs they are taking. Study visits are once a month and the study lasts 24 weeks.

Required:

- CD4 cell (T-cell) range: more than 100
- Viral load range: at least 5,000 copies/mL
- HIV positive
- At least 16 years old
- Must currently be taking hard gel saquinavir capsules (Invirase) for more than three months and be on the same antiretroviral medications for at least the last three weeks

Not allowed:

- Active opportunistic infections
- Prior use of any other protease inhibitor other than hard gel saquinavir (Invirase) for two weeks or longer
- Women who are pregnant or breastfeeding
- Patients on maintenance therapy for MAC, CMV retinitis, tuberculosis or toxoplasmosis
- Chronic diarrhea lasting for 14 days or longer
- Unexplained fever (101.5 F) lasting for 14 days or longer
- Any cancers other than KS of the skin that require chemotherapy or radiation therapy
- Patients that require blood transfusions
- Use of any investigational drug within four weeks of study entry

Location:

Pacific Oaks Research Group
Anne Blackburn, RN
(310) 360-8800

Tower Infectious Diseases
Tim Jordan, RN
(310) 358-2300 ext. 114

55. HIV Infection: bis-POM PMEA

Title:

CPCRA 039: A Phase II, Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of Adefovir Dipivoxil (bis-POM PMEA) in Prolonging Survival of HIV-Infected Individuals With a CD4+ Cell Count of 100/mm^3 or Less

Type of treatment:

bis-POM PMEA: antiretroviral, reverse transcriptase inhibitor, nucleotide analog

Purpose:

Toi see if bis-POM PMEA is safe and effective in prolonging survival of patients with advanced HIV disease. To see if bis-POM PMEA is effective in preventing the development of CMV end-organ disease in patients with advanced HIV disease who are also infected with HIV.
About the study:
Patients are assigned by chance to receive bis-POM PMEA or placebo. Neither patients nor their doctors will know which they are taking until the study ends. Both bis-POM PMEA and its placebo are pills and taken once a day. Patients will also take one pill per day of a supplement called L-carnitine. For the first 400 patients to enroll nationally, study vistits will be two weeks after the baseline visit, then every month for six months, then every other month until month 12. After 12 months, study visits will be every four months. Patients who enroll after the first 400 will have study visits at month 1, month 2, month 4, then every four months. Patients will be on this study at least 20 months.

Required:

- CD4 cell (T-cell) range: 100 or less
- Viral load range: not applicable
- HIV positive
- At least 13 years old

Not allowed:

- Past or current CMV organ disease, such as retinitis or colitis
- Women who are pregnant or breastfeeding
- Use of foscarnet within 60 days of study entry
- Use of any of the following within two weeks of study entry; acyclovir (more than 1 gram/day), cidofovir, famciclovir, ganciclovir, 123W94, ISIS 2922, lobucavir, MSL 109, valacyclovir
- Any condition that would require the use of the above-mentioned medica tions

Location:

Community Consortium
To be arranged through physician-see page 119
(415) 476-9554

56. HIV Infection: Nelfinavir, Ritonavir

Title:

CPCRA 042: A Randomized Trial of the Efficacy and Safety of Nelfinavir Versus Ritonavir Added to a Backround Antiretroviral Nucleoside Therapy in HIV-Infected Individuals With CD4+ Cell Counts of 100/mm^3 or Less

Type of treatment:

Nelfinavir: antiretroviral, protease inhibitor
Ritonavir: antiretroviral, protease inhibitor

Purpose:

To compare nelfinavir to ritonavir when added to backround antiretroviral therapy in terms of delaying disease progression and to measure safety.

About the study:

Patients are assigned by chance to receive nelfinavir or ritonavir to take with their antiretroviral therapy. Patients who are not taking any antiretroviral therapy are eligible to join, although the use of protease inhibitors by themselves is not recommended unless there is no other alternative. Patients will be allowed to switch to the other protease inhibitor if they experience disease progression or cannot tolerate their assigned medication. Both nelfinavir and ritonavir are pills and taken by mouth. There will be a one-month study visit after the screening visit, then every four months thereafter. The study lasts at least 18 months.

Required:

- CD4 cell (T-cell) ramge: 100 or less
- Viral load range: not applicable
- HIV Positive
- At least 13 years old

Not allowed:

- Prior use of any protease inhibitors other than saquinavir
- Severe AIDS dementia complex
- Women who are pregnant or breastfeeding
- Current use of protease inhibitors during the study

Location:

Community Consortium
To be arranged through physician-see page 119
(415) 476-9554

57. HIV Infection: Stress Management

Title:

REIMH57223: Coping Effectiveness Trial of HIV+ Men: The Changes Project

Type of treatment:

Psychosocial Intervention:

Purpose:

To identify and examine the most effective ways to handle the stress related to HIV disease, particularly in the changing environment created by new drug treatments. It is also believed that the research may provide some strong data to help improve HIV health care guidelines and policies.

About the study:

Participants are assigned by chance to one of three research groups. The first group of men will receive periodic check-in phone calls to survey their individual perspectives about the ongoing changes in the HIV epidemic, and then will attend a series of three stress management workshops. The second group will receive a 3-month stress management training program followed by a series of frequent booster sessions. The third group will receive the same 3-month stress management training program followed by less frequent booster sessions. Participants in groups and workshops will meet to talk about the stresses they feel as a result of being HIV positive today and share ways to cope more effectively. The study lasts one year.

Required:

- CD4 cell (T-cell) range: more than 50
- HIV positive
- Gay men only
- At least 21 years old
- Must remain in San Francisco Bay Area for the next 12 months

Not allowed:

- Female patients

Location:

UCSF Center for AIDS Prevention Studies
Changes Project
(415) 597-9169

58. HIV Viral Load: Observational

Title:

CC035: A Descriptive, Observational Study of the Natural History of the State of Undectectable HIV RNA Induced by Combination Antiretroviral Therapy

Type of treatment:

None: observational, natural history

Purpose:

To collect data from patients who have had a drop in the HIV RNA viral load to undectable levels. To observe viral load levels over time, changed in CD4 (T-cell) counts and to observe HIV-related illnesses.

About the study:

This is an information collecting study. Patients will have data from their medical charts collected by research study staff. The data collected will include routine laboratory test results, medication dosages and frequencies, and HIV-related illnesses. Data will be collected every four months. During routine office visits, patients may be asked about their health and medications by research study staff. These questions will require about two to three minutes. The study lasts three years.

Required:

- HIV positive
- Documented viral load of at least 1,500 copies/mL prior to initiation or change in combination antiretroviral therapy **AND** a docu mented viral load of less than 500 copies/mL within 120 days after initiating/changing therapy
- At least 13 years old

Not allowed:

- People planning to move away from the Bay Area

Location:

Community Consortium
To be arranged through physician-see page 119
(415) 476-9554

59. HIV-Associated Anemia: Marrow Plus

Title:

CC030: A Prospective, Randomized, Double-Blind Placebo-Controlled Pilot Study of Chinese Herbs (Marrow Plus) in Mild to Moderate HIV-Associated Anemia

Type of treatment:

Marrow Plus: Chinese herbal formula

Purpose:

To see if Marrow Plus, a Chinese herbal formula, is safe and effective in treating mild to moderate HIV-associated anemia.

About the study:

Patients are assigned by chance to receive Marrow Plus or placebo. Neither patients nor their doctors will know which they are receiving until the study ends. Marrow Plus and its placebo are pills and taken by mouth. Patients will be instructed to take four pills four times a day for 12 weeks. Study visits are once a month. The study lasts 12 weeks. After 12 weeks, patients may elect to take open-label (real) Marrow Plus for an additional 12 weeks.

Required:

- HIV positive
- At least 17 years old
- Mild to moderate anemia, defined as hemoglobin greater than or equal to 9 g/dl and less than or equal to 12 g/dl (11 g/dl for women)

Not allowed:

- Use of erythropoietin or blood transfusions to treat anemia
- Allergies to Chinese herbs
- Women who are pregnant or breastfeeding

Location:

Quan Yin Healing Arts Center
Carla Wilson
(415) 861-4964

Community Consortium
To be arranged through physician-see page 119
(415) 476-9554

60. Aphthous Ulcer Treatment: Thalidomide

Title:

R002: A Double-Blind, Dose Comparison Trial of Thalidomide for the Treatment of Recurrent or Refractory Aphthous Stomatitis (RAS) in HIV-Infected Patients

Type of treatment:

Thalidomide: cytokine inhibitor, antiwasting

Purpose:

To see if thalidomide is safe and effective in treating oral aphthous ulcers and to see if thalidomide is safe and effective in preventing oral aphthous ulcers from coming back.

About the study:

Patients are assigned by chance to receive one of three doses of thalidomide for 28 days of treatment. Neither patients nor their doctors will know which dose they are receiving until the study ends. Thalidomide is a pill and taken by mouth at bedtime. Study visits are once a week during this treatment phase of the study. Patients who respond to treatment within 28 days will be eligible for the maintenance treatment portion of the study. These patients will be assigned by chance to receive thalidomide or placebo for up to one year or sooner if relapse occurs. Study visits will be once a month for this portion of the study. Patients who do not respond to four weeks of treatment, who discontinue the study due to treatment failure, or who relapse will have the option of receiving thalidomide under a compassionate use protocol. The study lasts about one year.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 13 years old
- Must be receiving treatment with at least two antiretroviral medications, preferably one being a protease inhibitor, and antiretroviral therapy must have been stable (no changes) for at least four weeks prior to study entry and for at least four weeks into the study
- Biopsy-confirmed aphthous stomatitis (oral ulcer)
- Females of childbearing potential must refrain from sexual intercourse **OR** practice **TWO** methods of contraception; one barrier and one hormonal

Not allowed:

- Women who are pregnant or breastfeeding
- Positive oral culture for herpes simplex
- Use of corticosteroids within 14 days of study entry
- Severe peripheral neuropathy

Location:

Kaiser San Francisco - HIV Research Unit
Joseph Thatcher, RN, MSN
(415) 202-2529

61. Bacterial Infection Treatment: ABCD, Fungizone

Title:

SEQUUS-07-26/B: A Double-Blind, Randomized Study Comparing ABCD (Amphotericin B Colloidal Dispersion) and Fungizone in the Treatment of Febrile Neutropenic Patients Failing Broad Spectrum Antibacterial Therapy

Type of treatment:

Amphotericin B Colloidal Dispersion: anti-fungal
Amphotericin B: antifungal

Purpose:

To compare the incidence of side effects between ABCD and Fungizone (Amphotericin B) treated patients.

About the study:

Patients in this study will be assigned by chance to receive ABCD or Fungizone to treat their infection. Both medications are given by infusion into a vein. Infusions are given once a day. Neither patients nor their doctors will know which they are receiving until the study ends. Study visits are every three days. Patients will be on this study until the doctor feels treatment is no longer necessary.

Required:

- CD4 cell (T-cell) range: not applicable
- At least 2 years old
- Must have a low white cell count due to treatment with broad spectrum antibiotics for an infection

Not allowed:

- No exclusions

Location:

LAC-USC Medical Center - Maternal Child Program
Melissa Scanlon, RN
(213) 226-5095

62. Cervical Dysplasia Prevention: Isotretinoin

Title:

ACTG 293: A Randomized, Phase III Trial of Oral Isotretinoin versus Observation for Low Grade Cervical Dysplasia in HIV-Infected Women

Type of treatment:

Isotretinoin: skin cell growth stimulant

Purpose:

To see if oral isotretinoin is effective in preventing progression of mild dysplasia to more severe dysplasia by comparing the time to progression of Cervical Intraepithelial Neoplasia (CIN) I to CIN II, III or invasive cancer in patients receiving isotretinoin versus observation.

About the study:

Patients are assigned by chance to receive oral isotretinoin or to be observed. Isotretinoin is a pill and taken by mouth once a day for six months. Study visits are once a month for six months; then one visit at months 12 and 18. Some locations may pay patients for their participation.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- Females only
- At least 13 years old
- Diagnosis of CIN I by cervical biopsy (done by research staff at the test site)

Not allowed:

- CIN II, III, or invasive cervical cancer
- Any cancer requiring systemic chemotherapy within three months prior to study entry
- Previous use of isotretinoin within three months prior to study entry
- Past topical treatment for genital warts within one month prior to study entry
- Past treatment for CIN II or III
- Pregnancy or breastfeeding

Location:

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

UCSF AIDS Program at SFGH/ACTU
Kathy Dybeck, RN
(415) 476-9296 ext. 353

LAC-USC Medical Center
Luis Mendez, RN
(213) 343-8288

LAC-USC Medical Center - Maternal Child Program
Melissa Scanlon, RN
(213) 226-5095

AIDS Community Research Consortium
Sharon O'Leary, RN
(650) 364-6563

63. Cervical Dysplasia Treatment: DFMO

Title:

DFMO-96-001: A Phase II Study of the Efficacy and Safety of Orally Administered DFMO in HIV-Infected Women With Cervical Intraepithelial Neoplasia (CIN II, III)

Type of treatment:

DFMO: anti-cancer

Purpose:

To see if DFMO is safe and effective for HIV positive women who have Cervical Intraepithelial Neoplasia (CIN), a pre-cancerous condition.

About the study:

Women will be screened with a cervical examination, a Pap smear and a colposcopy, including a biopsy if any abnormality is suspected. Women who have biopsy-proven CIN will be enrolled in the study. All women entering this

study will take DFMO. DFMO is a liquid which is mixed with another beverage and is taken by mouth. The dose will depend upon the patients' size and weight. Patients will drink DFMO once a day every day for three months. After three months, patients will have another colposcopy performed. There are two screening visits, then study visits once a month. The study lasts about three and a half months. Some study sites may reimburse patients for each study visit.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: not applicable
- HIV positive
- At least 18 years old
- Biopsy-proven (within eight weeks of study entry) CIN, grade II or III

Not allowed:

- Any other active cancers within the last five years
- Women who are pregnant or breastfeeding
- Currently participating in any investigational drug trial

Location:

AIDS Healthcare Foundation
Heather Churchill, RN
(213) 913-3953

64. Oral/Esophageal Candidiasis Treatment: Itraconazole

Title:

ITR-USA-109: An Open-Label, Non-Comparative Trial of Itraconazole Solution for the Treatment of Patients with Oropharyngeal/Esophageal Candidiasis Nonresponsive to Fluconazole

Type of treatment:

Itraconazole: antifungal

Purpose:

To see if itraconazole oral solution is safe and effective for treating oral or esophageal thrush (candidiasis) for patients whose thrush did not get better when taking fluconazole. This study will also provide itraconazole to patients unable to participate in other trials.

About the study:

All patients entering this study will receive open-label (real) itraconazole once a day for four weeks. This form of itraconazole is a liquid and is swallowed. After four weeks, patients either stop taking the drug if their thrush has gotten worse, or continue for two more weeks. After six weeks, patients whose thrush has gone away will continue on a lower dose (3 times a week) indefinitely. All others discontinue the drug.

Required:

- CD4 cell (T-cell) range: not specified
- At least 13 years old
- Oral and/or esophageal thrush (candidiasis)
- Must have failed fluconazole 200 mg/day for a minimum of two weeks

Not allowed:

- Women who are pregnant or breastfeeding
- Liver disease

Location:

Tower Infectious Diseases
Tim Jordan, RN
(310) 358-2300 ext. 114

65. Oral/Esophageal Candidiasis Treatment: Amphotericin B Colloidal Dispersion

Title:

SEQU-07-32: A Double-Blind, Randomized, Multi-Center Study of the Safety, Efficacy and Toleration of Three Doses of Amphotericin B Colloidal Dispersion (ABCD) versus Amphotericin B in the Treatment of Oropharyngeal Candidiasis (OPC) and Esophageal Candidiasis Failing Azole Therapy in AIDS Patients

Type of treatment:

Amphotericin B Colloidal Dispersion: anti-fungal
Amphotericin B: antifungal

Purpose:

To see which dose of amphotericin B colloidal dispersion (ABCD) is most effective in responding to fluconazole-resistant oral/esophageal candidiasis.
To see how ABCD compares to amphotericin B in treatment response.
To see how effective ABCD is for maintenance for oral/esophageal candida.

About the study:

Amphotericin B colloidal dispersion (ABCD) is a form of amphotericin B that has been suspended in a solution of fats, which may be better tolerated. For the induction phase, patients are assigned by chance to receive one of three doses of ABCD or to receive amphotericin B. Neither patients nor their doctors will know which drug or which dose they are receiving until the study ends. ABCD and amphotericin B are both given by infusion into a vein. Infusions are given every day for seven days. If needed, patients may receive an additional seven days for a total of 14 days. Patients who respond partially or completely are eligible to for the maintenance phase. They will be

assigned by chance to one of two doses of ABCD. Infusions will be once or twice a week and the maintenance phase lasts three months. The study lasts four months.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: not applicable
- HIV positive
- Between 1 and 99 years old
- Active oral and/or esophageal candidiasis
- Failure to get better with at least five days of fluconazole therapy. This failure must have occured within six months prior to this episode *Positive culture for candida

Not allowed:

- Women who are pregnant or breastfeeding
- Known allergy or sensitivity to amphotericin B
- Use of other medications for candidiasis which cannot be discontinued
- Candidiasis that has desseminated to internal organs
- Use of more than 5mg/kg of amphotericin B in the past seven days

Location:

Tower Infectious Diseases
Tim Jordan, RN
(310) 358-2300 ext. 114

66. Oropharyngeal Candidiasis Treatment: Fluconazole

Title:

ACTG 323/MSG 40: A Phase III Randomized Study of the Use of Fluconazole as Chronic Suppressive Therapy Versus Episodic Therapy in HIV Positive Subjects With Reccurent Oropharyngeal Candidiasis

Type of treatment:

Fluconazole: antifungal

Purpose:

To find out if it is better to take fluconazole three times a week to prevent thrush or esophageal candidiasis from coming back, or to wait until you get thrush or esophageal candidiasis again before taking it.

About the study:

Patients are assigned by chance to take fluconazole three times a week, or to take fluconazole only if they get thrush or esophageal candidiasis. There are no placebos in this study. Patients who join the study when they have thrush or esophageal candidiasis will be treated with fluconazole first, and then assigned by chance to take fluconazole every week, or to wait until they get thrush or esophageal candidiasis again. Study visits are every two months. Blood samples are drawn at each study visit. The study lasts two years.

Required:

- CD4 cell (T-cell) range: 150 or less
- HIV positive
- At least 13 years old
- At least one episode of oropharyngeal candidiasis (thrush) within the past six months

Not allowed:

- Three or more episodes of oropharyngeal candidiasis within the past three months
- Prior esophageal candidiasis
- Women who are pregnant or breastfeeding
- Any fungal infection requiring treatment with amphotericin-B, terbinafine, Lamisil or Ancoban
- Acute or active opportunistic infection requiring treatment

Location:

UCSF AIDS Program at SFGH/ACTU
Kathy Dybeck, RN
(415) 476-9296 ext. 353

67. Oral/Esophageal Candidiasis Treatment: MK-0991, Amphotericin-B

Title:

004-03: A Multiclinic, Double-Blind, Randomized Comparative Dose-Response Study to Evaluate the Safety, Tolerability and Efficacy of MK-0991 versus Amphotericin-B in the Treatment of Oropharyngeal and Esophageal Candidiasis in Adults

Type of treatment:

Amphotericin B: antifungal
MK-0991: antifungal

Purpose:

To see if MK-0991 is safe and well tolerated and to compare MK-0991 and amphotericin B to see which is more effective in treating candidiasis.

About the study:

Patients are assigned by chance to receive one of three doses of MK-0991 or to receive amphotericin-B. Both MK-0991 and amphotericin-B are given by infusion into a vein. Infusions will be given every day for 14 days and patients will need to come to the hospital for these infusions. Neither patients nor their doctors will know which they are receiving until the study ends. Study visits are every day for infusions, one visit three to four days after treatment and at weeks two and four. The study lasts two months.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Between 18 and 65 years old
- Diagnosis of oral or esophageal candidiasis for which IV therapy is appropriate

Not allowed:

- Women who are pregnant or breastfeeding
- Current opportunistic infection requiring acute therapy
- Esophagitis with another cause (such as CMV) in addition to Candida
- Acute or chronic hepatitis or cirrhosis
- Concurrent use of rifampin, ritonavir

Location:

UCSF AIDS Program at SFGH/ICTG
Anna Smith, RN
(415) 476-9296, ext. 313

68. Oropharyngeal Candidiasis Treatment: SCH 56592

Title:

C96-209: A Multicenter, Randomized, Double-Blind, Phase II Study to Evaluate the Safety, Tolerance and Efficacy of Multiple Doses of SCH 56592 Versus Fluconazole in the Treatment of Oropharyngeal Candidiasis (OPC) in HIV-Positive Patients

Type of treatment:

SCH 56592: antifungal
Fluconazole: antifungal

Purpose:

To see if the new drug SCH 56592 is safe and effective in treating oropharyngeal candidiasis (also called thrush). To see which dose of SCH 56592 is safest and most effective.

About the study:

Patients are assigned by chance to receive one of four doses of SCH 56592 or to receive fluconazole for 13 days. All patients will receive medication; there are no placebos in this study. Neither patients nor their doctors will know which medication or which dose they are taking until the study ends. Both medications are pills and taken by mouth. Study visits are once a week for the first two weeks, then every two weeks for two visits. Some sites may pay participants for completing the study.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Between 18 and 65 years old
- Symptomatic oral candidiasis

Not allowed:

- Active, acute infections other than OPC (thrush)
- Use of amphotericin B within 30 days of study entry and throughout the study
- Use of rifampin, carbamazepine, phentoin, rifabutin, barbituates or isoniazid (INH) within 30 days of study entry and throughout the study
- Changes in antiretroviral therapy within 30 days of study entry
- Use of chemotherapy other than ART
- Use of systemic antifungals other than amphotericin B within 14 days of study entry
- Esophageal candidiasis
- Women who are pregnant or breastfeeding

Location:

East Bay AIDS Center
Nancy Orcutt, RN, MS
(510) 204-1291

69. CMV Infection: 1263W94

Title:

CMAA1003: A Phase I/II Trial to Evaluate the Tolerability, Anti-CMV Effect and Pharmacokinetics of 1263W94 Following Multiple Oral Administration of Escalating Doses in HIV-Infected Patients with Asymptomatic CMV Shedding

Type of treatment:

1263W94: antiviral

Purpose:

To see if the new drug 1263W94 is safe and to see if it has any anti-CMV effects. To see how 1263W94 is processed by the body.

About the study:

Patients entering this study will be required to have urine and semen samples tested for CMV. Patients with 100 or less T-cells will also have an eye exam for CMV retinitis. This is a dose escalating study. This means that the first group of patients to enter the study will receive the lowest dose of 1263W94. If no bad side effects are observed, the next group of patients will receive a higher dose and so forth until the highest dose of 1263W94 that researchers plan to study has been given. Patients will know which dose they are receiving. 1263W94 is a pill and is taken by mouth three times a day. On days 1 and 28, patients will be admitted to the hospital for 24 hours. These visits are for timed blood tests. Patients will have a temporary catheter placed in their forearm for these visits. Patients will be treated for 28 days. Study visits are once a week. Patients will return to the clinic four weeks after completing treatment for a final study visit. Patients are paid $410 for completing this study.

Required:

- CD4 cell (T-cell) range: 150 or less
- Viral load range: not applicable
- Male patients only
- At least 18 years old
- HIV positive
- Must be on stable antiretroviral therapy or prophylaxis

Not allowed:

- Active CMV disease, such as retinitis, colitis, encephalitis or pneumonitis

- Vision symptoms of CMV disease such as floaters, decreased visual acuity **UNLESS** CMV disease is excluded with an eye examination
- Previous therapy with ganciclovir, foscarnet, cidofovir (HPMPC) within two months prior to study entry
- Treatment with interferons, immunomodulators or CMV hyperimmune globulin within one month prior to study entry
- Active hepatitis or other liver diseases
- Gastrointestinal disorders which may interfere with the study such as chronic nausea/vomiting, persistent diarrhea
- Treatment with radiation, chemotherapy within one month of study entry or the need for such during the study
- Known history of lactose intolerance

Location:

UCSF AIDS Program at SFGH/ICTG
Dorie Heeren, RN
(415) 476-9296, ext. 305

Quest Clinical Research, San Francisco
Eileen Glutzer, RN
(415) 353-0800

70. CMV Retinitis Treatment: ISIS 2922

Title:

ISIS 2922-CS2: A Randomized Comparison of Immediate versus Delayed Treatment with Intravitreal Injections of ISIS 2922 in Patients with Peripheral Cytomegalovirus (CMV) Retinitis

Type of treatment:

ISIS 2922: antiviral

Purpose:

To find out if a new treatment for CMV retinitis, called ISIS 2922, is safe and effective.

About the study:

Patients are assigned by chance to receive either immediate or delayed treatment with ISIS 2922. Patients assigned to delayed treatment will receive ISIS 2922 if their CMV retinitis begins to spread. ISIS 2922 is given by injection into the eye. Injections are given once a week for three weeks, and then once every other week. At each visit, patients will have an eye exam and have blood tests performed. The study lasts 20 weeks.

Required:

- CD4 cell (T-cell) range: not specified
- Diagnosis of CMV retinitis in one eye, previously untreated
- At least 18 years old

Not allowed:

- Certain eye infections or other diseases of the eye
- Patients with retinal detachments
- Previous treatment for CMV retinitis
- Less than 10,000 platelets
- Women who are pregnant or breastfeeding

Location:

AIDS Community Research Consortium
Debbie Slamowitz, RN
(650) 364-6563

Community Eye Medical - Brian G. Terry, MD
Ramon Bautista
(626) 584-1200

Retina-Vitreous Group - David Boyer, MD
Stone Blacka, CRC
(310) 854-6201

71. CMV Retinitis Treatment: ISIS 2922, Ganciclovir

Title:

ISIS 2922-CS3: A Randomized Comparison of Intravitreal ISIS 2922 plus Ganciclovir versus Ganciclovir as Treatment for Patients with Cytomegalovirus (CMV) Retinitis

Type of treatment:

ISIS 2922: antiviral
Ganciclovir, IV: antiviral

Purpose:

To test the safety and effectiveness of a new drug called ISIS 2922 in combination with ganciclovir compared to ganciclovir alone for treatment of CMV retinitis.

About the study:

Patients are assigned by chance to receive ISIS 2922 plus ganciclovir or ganciclovir alone. ISIS 2922 is given by injection into the eye. Injections of ISIS 2922 are given every week for three weeks and then every other week until the end of the study. Ganciclovir is given by injection into a vein every 12 hours for 14 days. Patients who receive ganciclovir by injection can have a central line placed so they can receive injections at home. A central line is a small tube (catheter) semi-permanently inserted into a vein, often in the upper chest just below the collar bone. It will be removed at the end of the study. Patients taking ganciclovir will be referred to a home health agency so they can receive ganciclovir injections at home. After 14 days, patients will take ganciclovir tablets until the end of the study. At each visit, patients will have an eye exam and have blood tests performed. The study lasts 20 weeks.

Required:

- CD4 cell (T-cell) range: not specified
- At least 18 years old
- Diagnosis of CMV which has not improved with other treatments

Not allowed:

- Certain eye infections or other diseases of the eye to be treated
- Patients with retinal detachments
- Prior treatment with ganciclovir implants or treatment with ganciclovir for more than 4 months
- Patients who have had CMV before
- Chronic diarrhea
- Less then 10,000 platelets
- Pregnant or breastfeeding women

Location:

AIDS Community Research Consortium
Debbie Slamowitz, RN
(650) 364-6563

Community Eye Medical - Brian G. Terry, MD
Ramon Bautista
(626) 584-1200

Retina-Vitreous Group - David Boyer, MD
Stone Blacka, CRC
(310) 854-6201

72. CMV Retinitis Treatment: ISIS 2922 (2)

Title:

ISIS 2922-CS9: A Randomized Comparison of Two Dosage Schedules of Intravitreal ISIS 2922 for Patients with Advanced Cytomegalovirus Retinitis

Type of treatment:

ISIS 2922: antiviral

Purpose:

To find a safe and effective dose of the new treatment called ISIS 2922 for advanced CMV retinitis.

About the study:

Patients are assigned by chance to receive ISIS 2922 either every other week, or every week for 3 weeks, then every other week until the end of the study. ISIS 2922 is given by injection into the eye. The study lasts 22 weeks. Study visits are every week for the first 3 weeks, then every other week until the end of the study.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- Diagnosis of advanced CMV retinitis in one or both eyes
- At least two previous anti-CMV retinitis therapies
- At least 18 years old

Not allowed:

- Previous ganciclovir implants
- Psuedoretinitis pigmentosa infection
- Syphilis, past or present
- Pregnant or nursing women

Location:

UCSF AIDS Program at SFGH/ICTG
Joe Rebholz
(415) 476-9296 ext. 310

UC Irvine Department of Ophthalmology
Karen Lopez, BS, COA
(714) 824-8303

Community Eye Medical - Brian G. Terry, MD
Ramon Bautista
(626) 584-1200

Retina-Vitreous Group - David Boyer MD
Stone Blacka, CRC
(310) 854-6201

73. CMV Retinitis Treatment: ISIS 2992

Title:

ISIS 2922-CS7: An Open-Label Study of the Safety and Efficacy of Intravitreal ISIS 2922 in Acquired Immune Deficiency Syndrome (AIDS) Patients With Cytomegalovirus Retinitis (NOTE: Restricted to Patients Who Rollover From Another Controlled ISIS 2922 Trial)

Type of treatment:

ISIS 2922: antiviral

Purpose:

To see if ISIS 2922 is safe and effective for treating CMV retinitis in patients who cannot take or were not helped by ganciclovir and/or foscarnet OR have failed ISIS 2992 therapy on another controlled clinical trial.

About the study:

Patients in this study must rollover from another ISIS 2922 controlled trial. Patients will receive intravitreal injections (injections into the eyeball) of ISIS 2922 at one of two doses depending on the location and severity of their retinitis. There ia a three-week induction period followed by a maintenance period of at least 18 weeks. Induction is given on days 1, 8 and 15 and maintenance doses are given every 14 days, beginning on day 29. The study lasts at least 21 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- CMV retinitis in one or both eyes that was previously treated but is presently uncontrolled
- Not able to take, or unresponsive to other therapies
- Patients must rollover from another ISIS 2922 trial
- At least 18 years old

Not allowed:

- Women who are pregnant or breastfeeding
- Prior surgery to correct retinal detachment
- Past use of ganciclovir implants
- Past or current syphilis

Location:

AIDS Community Research Consortium
Debbie Slamowitz, RN
(650) 364-6563

UC Irvine Department of Ophthalmology
Karen Lopez, BS, COA
(714) 824-8303

Community Eye Medical - Brian G. Terry, MD
Ramon Bautista
(626) 584-1200

Retina-Vitreous Group - David Boyer, MD
Stone Blacka, CRC
(310) 854-6201

74. CMV Retinitis Treatment: VIRACEPT (nelfinavir), Ganciclovir

Title:

AG1343-517: A Randomized, Placebo-Controlled Study to Determine the Effects of VIRACEPT (Agouron Protease Inhibitor) on the Outcome of CMV Retinitis in AIDS Patients who are Receiving Standard Induction and Maintenance Therapy for CMV Infection

Type of treatment:

Nelfinavir: antiretroviral, protease inhibitor
Ganciclovir, IV: antiviral

Purpose:

To compare the time of progression of CMV retinitis in patients receiving ganciclovir for their CMV retinitis versus those receiving ganciclovir plus VIRACEPT (nelfinavir).

About the study:

Patients are assigned by chance to receive VIRACEPT in addition to their ganciclovir or to receive placebo with their ganciclovir. Neither patients nor their doctors will know which they are receiving. After eight weeks, all patients will receive open-label (no placebo) VIRACEPT to take in addition to their ongoing ganciclovir treatment. VIRACEPT and its placebo are pills taken by mouth and patients will take nine pills a day. There are two screening visits. Study visits will be every two weeks for the first 12 weeks and will include a dilated eye exam and retinal photograph. After 12 weeks, study visits are once a month. The study lasts 12 months.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Newly diagnosed or first relapse of CMV retinitis

Not allowed:

- More than seven days of induction therapy for CMV retinitis

Location:

Harbor-UCLA Medical Center
Crystal Lane, RN
(310) 222-3848

75. CMV Retinitis Treatment: Intraocular Cidofovir

Title:

GS-96-503: A Phase I/II, Open-Label, Dose-Escalation Study on the Safety and Efficacy of Intraocular Cidofovir for the Treatment of Relapsing Cytomegalovirus Retinitis in Patients with AIDS

Type of treatment:

Cidofovir: antiviral

Purpose:

To see if injecting cidofovir into the eye is a safe and effective treatment for CMV retinitis.

About the study:

This is a dose escalation study. This means that the first patients to enroll on the study will receive the lowest dose of intravitreal cidofovir. If no bad side effects are seen, the next group will receive a higher dose of cidofovir, and so forth until the highest dose that researchers plan to study has been given. Cidofovir is given as an injection into the eyeball every six weeks. Study visits are every two weeks and the study lasts until CMV retinitis progression.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Between 13 and 60 years old
- Diagnosis of CMV retinitis

Not allowed:

- CMV disease outside of the eye
- Detached retina repaired by any other means than scleral buckle or laser
- Prior therapy with systemic or intraocular cidofovir

Location:

Quest Clinical Research, San Francisco
Eileen Glutzer, RN
(415) 353-0800

UC Irvine Department of Ophthalmology
Karen Lopez, BS, COA
(714) 824-8303

76. CMV Retinitis Treatment: RS-79070, IV Ganciclovir

Title:

WV15376B: A Randomized, Controlled Comparison of the Safety and Efficacy of RS-79070, an Oral Prodrug of Ganciclovir vs IV Ganciclovir as Induction Therapy for the Treatment of Newly Diagnosed Cytomegalovirus Retinitis

Type of treatment:

RS-79070: ganciclovir prodrug

Purpose:

To see if the ganciclovir prodrug RS-79070 is safe and effective when used as induction therapy in patients with newly diagnosed CMV retinitis. To see how RS-79070 affects the way ganciclovir is processed by the body and to see how RO-79070 affects CMV viral load.

About the study:

Patients with newly diagnosed CMV retinitis will be assigned by chance to receive either IV ganciclovir or RS-79070 for four weeks. IV ganciclovir is given by infusion into a vein. RS-79070 is a pill and taken by mouth. Patients will know which treatment they are receiving. Patients assigned to receive IV ganciclovir will have a small tube (catheter) semi-permanently inserted into a vein in their upper chest to receive drug. After four weeks, all patients will be offered oral RS-79070 for longterm follow-up. Study visits are once a week for four weeks. The study lasts four weeks but patients may then enroll onto the longterm follow-up study which will have study visits every two weeks until progression of CMV retinitis.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Newly diagnosed with peripheral CMV retinitis

Not allowed:

- Women who are pregnant or breastfeeding
- Past CMV disease, such as retinitis, colitis or esophagitis
- Past surgery to the stomach or small intestine
- Prior use of any anti-CMV treatments such as ganciclovir, foscarnet, cidofovir or any investigational anti-CMV drugs

Location:

Kaiser San Francisco Ophthalmology
Anna Dowling, RN
(415) 202-3981

Pacific Oaks Research Group
Anne Blackburn, RN
(310) 360-8800

UCSD Treatment Center
Anne French, RN
(619) 543-8080 ext. 238

Davies Medical Center HIV Institute
Bettina Sporkenbach, RN
(415) 565-6163

Quest Clinical Research, San Francisco
Jacob Lalezari, MD
(415) 353-0800

UC Irvine Department of Ophthalmology
Karen Lopez, BS, COA
(714) 824-8303

77. CMV Retinitis Treatment: GEM 132

Title:

132-100: An Open-Label, Phase I/II Study of the Safety and Efficacy of Single Escalating Doses of Intraocular GEM 132 in AIDS Patients with Relapsing Cytomegalovirus (CMV) Retinitis

Type of treatment:

GEM 132: antiviral

Purpose:

To see if injecting GEM 132 into the eye is safe and to see if it is effective in treating CMV retinitis.

About the study:

The first group of patients to enter this study will receive the lowest dose of GEM 132. If no bad side effects are seen, the next group of patients will receive a higher dose, and so forth until the highest dose researchers plan to study has been given. GEM 132 is given as a single injection into the eyeball. Study visits are once a week for the first month, then every two weeks for an additional two months. Eye exams and blood tests will be performed at study visits.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- CMV retinitis that has gotten worse

Not allowed:

- Prior use of ganciclovir implants or intravitreal cidofovir in the eye to be studied

Location:

Kaiser San Francisco Ophthalmology
Anna Dowling, RN
(415) 202-3981

Quest Clinical Research, San Francisco
Jacob Lalezari, MD
(415) 353-0800

UC Irvine Department of Ophthalmology
Karen Lopez, BS, COA
(714) 824-8303

78. CMV Retinitis Treatment: Cidofovir, Ganciclovir

Title:

ACTG 350/GCCRT: The Ganciclovir and Cidofovir CMV Retinitis Trial (GCCRT)

Type of treatment:

Cidofovir: antiviral
Ganciclovir, eye implants: antiviral
Ganciclovir, oral: antiviral

Purpose:

To compare the use of cidofovir to the use of ganciclovir implants plus oral ganciclovir with respect to the effectiveness in preventing vision loss in patients with CMV retinitis.

About the study:

Patients are assigned by chance to receive intravenous cidofovir or to receive ganciclovir intraocular implants and oral ganciclovir. Patients will know which treatment they are receiving. Patients assigned to receive cidofovir will have cidofovir given intravenously once a week for the first two weeks, then once every two weeks thereafter. Patients assigned to ganciclovir will have an intraocular device surgically implanted at baseline and every six to eight months thereafter in eyes with CMV retinitis. Oral ganciclovir is a pill and patients take four pills three times a day. Study visits are every four weeks. The study lasts indefinitely.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 13 years old
- Active CMV retinitis
- Visual acuity of 20/100 or better in at least one eye
- At least one lesion 750 microns or greater in size that can be photographed

Not allowed:

- Previous CMV treatment with cidofovir or the ganciclovir intraocular device
- Allergy to probenecid or sulfa sepsis syndrome
- Clinically significant cardiac disease, ischemia, congestive heart failure or arrhythmia
- Women who are pregnant or breastfeeding
- Current alcohol or substance abuse

Location:

UCLA - Jules Stein Eye Institute
Catherine Strong
(310) 794-7868

LAC-USC Medical Center
Gil Clemente, RN
(213) 343-8284

UC Irvine Department of Ophthalmology
Karen Lopez, BS, COA
(714) 824-8303

79. CMV Retinitis Treatment: Ganciclovir, G-CSF

Title:

Ganciclovir and Neupogen Dose Escalation Study to Evaluate a Strategy to Achieve Individual Maximal Doses of Ganciclovir During Maintenance Therapy of CMV Retinitis

Type of treatment:

Ganciclovir, IV: antiviral
G-CSF: white blood cell stimulator

Purpose:

To treat patients with the highest tolerated dose of ganciclovir during maintenance therapy for CMV retinitis through the use of high doses of Neupogen (G-CSF). To see if this treatment can help prevent a relapse of CMV retinitis.

About the study:

This is a dose-escalation study. This means that patients will receive ganciclovir in increasing doses over time. Patients will also receive Neupogen (G-CSF) to help prevent a reduction in white blood cells. Ganciclovir is given by infusion into a vein every day and Neupogen is given by injection under the skin three times a week. Study visits are once a week and the study lasts nine months.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- First episode or first relapse only of CMV retinitis

Not allowed:

- Patients using foscarnet must discontinue and switch to ganciclovir
- Any condition requiring chemotherapy
- KS of the lungs

Location:

LAC-USC Medical Center
Connie Olson, RN
(213) 343-8279

80. Cryptococcal Meningitis Treatment: Fluconazole, Liposomal Amphotericin B

Title:

94-0-013: A Randomized, Double-Blind, Comparative Trial of Two Doses of Ambisome (Liposomal Amphotericin-B) Versus Amphotericin B, Followed by Fluconazole in the Treatment of Acute Cryptococcal Meningitis in AIDS Patients.

Type of treatment:

Fluconazole: antifungal
Amphotericin B, Liposomal: antifungal
Amphotericin B: antifungal

Purpose:

To see if the new liposomal formulation of Amphotericin B is safer and more effective than the older version in treating cryptococcal meningitis. To find out which dose of the new formulation is better.

About the study:

This study is testing a new formulation (called "liposomal") of the drug amphotericin B. The liposomal formulation means that the drug is packaged in fat molecules, which makes higher doses easier to tolerate. Fat molecules are also harder for the body to process, so the drug is not passed as quickly as in a non-liposomal version. This study is also a dose finding study, which means that the first group of people to join will receive a smaller dose of liposomal amphotericin B. If this dose is found to be safe, the next group will receive a higher dose. In this study, people are assigned by chance to receive either the new liposomal formulation or the standard formulation. Neither the patients nor their doctors will know which they are receiving until the study ends. Patients will receive fluconazole for 8 weeks after two weeks of amphotericin B treatment. Both formulations of amphotericin B are given as an infusion into a vein. Fluconazole is a pill. Samples of cerebrospinal fluid (CSF) will be taken. A tube is inserted between the bones of the spine in the lower back to collect a sample of CSF. The total length of the study is ten weeks.

Required:

- CD4 cell (T-cell) range: not specified
- Viral load range: unspecified
- Acute cryptococcal meningitis
- HIV positive
- Greater than 1 month old

Not allowed:

- Other systemic fungal infection at time of study entry
- History of anaphylaxis (severe allergic reaction) to amphotericin B
- Pregnant or nursing women

Location:

Kaiser San Francisco - HIV Research Unit
Gretchen Van Raalte, RN, MS
(415) 202-3482

UCSF AIDS Program at SFGH/ICTG
Nelson Murcar, RN
(415) 476-9296, ext. 333

81. AIDS Dementia Treatment: 1592U89

Title:

CNAB 3001: A Phase III, Randomized, Double-Blind, Multicenter Study to Evaluate the Safety and Efficacy of 1592U89 in HIV-1 Infected Patients with AIDS Dementia Complex Receiving Antiretroviral Therapy Either Approved or Expanded Access

Type of treatment:

1592U89: antiretroviral

Purpose:

To see if 1592U89 is safe, well-tolerated and to see if it can improve thought processes in patients with AIDS-related dementia.

About the study:

Patients are assigned by chance to receive 1592U89 or placebo. 1592U89 and its placebo are pills taken by mouth. Neither patients nor their doctors will know which they are taking until the study ends. After 12 weeks of treatment, patients will be offered open label (real) 1592U89 for an additional 40 weeks. Study visits are every two weeks for the first 12 weeks. After 12 weeks, patients participating in the open label portion of the study will have study visits every 2-4 weeks for the first eight weeks, then every 8 weeks for the remainder of the study. The study lasts 52 weeks. Patients are required to have a lumbar puncture (spinal tap) at the beginning of the study. Patients will be paid $100 for each spinal tap after the first one. Patients will also be paid $25 for each follow-up visit..

Required:

- CD4 cell (T-cell) range: not specified
- Viral load range: not specified
- Between 18 and 65 years old
- HIV positive
- Documented diagnosis of AIDS Dementia Complex
- Must be stable on current antiretroviral treatment for at least 8 weeks prior to study entry

Not allowed:

- Use of d4T is not allowed during this study
- Patients who currently have CNS infections or cancers
- Previous neurological disease unrelated to HIV such as multiple sclerosis, stroke, degenerative disease which may interfere with neurological testing
- Alcohol or illicit drug use which could interfere with the study
- Hepatitis or pancreatitis in the past 6 months
- Women who are pregnant or breastfeeding

- Use of radiation or chemotherapy within one month of study entry or the need for such during the next 12 weeks
- Use of any investigational antiretroviral trial or HIV vaccine trial in the past 3 months
- Use of immunomodulators, such as steroids, interleukins, thalidomide or interferons within the past month
- Use of nerve growth factor

Location:

SFGH Department of Neurology
Richard W. Price, MD
(415) 206-3208

82. AIDS Dementia Complex Treatment: Memantine

Title:

ACTG 301: A Phase II, Randomized, Double-Blind, Placebo-Controlled Trial of Memantine for AIDS Dementia Complex (ADC) As Concurrent Treatment with Antiretroviral Therapy

Type of treatment:

Memantine: antiviral

Purpose:

To see if memantine has any effect on improving AIDS Dementia Complex. To see if memantine may have any effect on relieving painful peripheral neuropathy in patients being treated with antietroviral therapy.

About the study:

Patients will be assigned by chance to receive memantine or placebo to take with their current antiretroviral treatment(s). Neither patients nor their doctors will know which they are taking until the study ends. Memantine is a pill and taken by mouth. In addition to the screening process, there are eight study visits, once a month. The study lasts 16 weeks. After 16 weeks, all patients will be offered real memantine (no placebo) for an additional 12 weeks. There are two lumbar punctures (spinal taps) required; one at screening, the second at 16 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: not applicable
- HIV positive
- At least 18 years old
- Diagnosis of AIDS Dementia Complex (ADC), stage 1, 2, or 3
- Must be on stable antiretroviral treatment for at least eight consecutive weeks prior to study entry AND maintain this treatment throughout the study
- Impaired cognitive function as evidenced by neuropsychological tests

Not allowed:

- Any cancers other then basal cell, cervical or KS of the skin
- Any psychiatric diagnosis, such as schizophrenia or severe bipolar illness, which may affect the analysis of the study
- Active AIDS-defining opportunistic infections
- Neurologic disease unrelated to HIV, such as multiple sclerosis, stroke, degenerative disease
- Seizure disorder
- CNS infections or neoplasms, such as toxoplasmosis, CNS lymphoma, PML, cryptococcal meningitis, untreated syphilis
- Women who are pregnant or breastfeeding
- Active alcohol or drug abuse which may interfere with the study
- Use of IV Pentamidine or use of calcium channel antagonists (high blood pressure medications) within 30 days prior to study entry

Location:

UCSD Treatment Center
Anne French, RN
(619) 543-8080 ext. 238

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

UCSF AIDS Program at SFGH/ACTU
Kathy Dybeck, RN
(415) 476-9296 ext. 353

Harbor-UCLA Medical Center
Mario Guerrero
(310) 222-3848

UCSF AIDS Clinic
Sue Forstat, LVN
(415) 476-3226

New

83. AIDS Dementia Complex Treatment: 1592U89

Title:

Kinetic Studies of Cerebrospinal Fluid (CSF) in Severe AIDS Dementia Complex Treated with a New Antiviral Drug, 1592U89

Type of treatment:

1592U89: antiretroviral

Purpose:

To see if 1592U89 is effective in reducing the amount of HIV virus in the central nervous system (spinal fluid) and in the blood. To see if 1592U89 helps treat AIDS dementia.

About the study:

All patients will take 1592U89 twice a day. 1592U89 is a pill and taken by mouth. Patients will have six lumbar punctures (spinal taps) during this study. A spinal tap is a needle passed into the spinal column between vertebra and having some fluid removed. Patients are paid $50 for the first spinal tap, $75 for the second, and $100 for the remaining four taps. Study visits are twice a week for the first two weeks,

then at one month. Patients who did not have a visit at day 10 will have a visit at week 52. The study lasts one month, or for some, one year.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: more than 25,000 copies/mL
- CSF viral load range: more than 1,000 copies/mL
- HIV positive
- At least 18 years old
- Must have a diagnosis of AIDS Dementia Complex, Stage 3 or 4
- Must be on stable antiretroviral (no changes) therapy for at least six weeks prior to study entry

Not allowed:

- Any other neurological disease or complications, such as lymphoma, toxoplasmosis or meningitis
- Active or chronic infections that might interfere with the study

Location:

SFGH Department of Neurology
Richard W. Price, MD
(415) 206-3208

84. Diarrhea Treatment: Octreotide

Title:

Continuous Subcutaneous Administration of Octreotide for Refractory AIDS-Associated Diarrhea

Type of treatment:

Octreotide: digestive hormone

Purpose:

To find out if giving octreotide continuously (all day, instead of a few times a day) is more effective in relieving diarrhea that does not respond to (or comes back after) other treatments.

About the study:

All patients receive the treatments Pancrease MT16 and Octreotide. Pancrease MT16 is an enzyme supplement that will help the body tolerate octreotide better. Everyone must keep a diary of their bowel movements every day of the study. On certain days, you will be asked to weigh your bowel movements with special equipment provided by the study. After one week of taking Pancrease MT16 pills, you will be shown how to give yourself subcutaneous infusions of octreotide. These are given using a pump and a small tube that is attached to a small needle that is inserted under the skin of your abdomen (stomach area). The dose of octreotide is increased each week for three weeks, for a total of four weeks. Participants are reimbursed $500 for completing the study.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- At least 18 years old
- Diarrhea of a certain quantity for at least two weeks in a row
- If diarrhea is due to parasites such as *cryptosporidium*, Isospora belli, or microsporidia, participants must either be on stable treatment, or no treatment at all, and must agree not to change treatment during the study.

Not allowed:

- Diarrhea due to a treatable cause
- Active CMV of the gastrointestinal tract
- History of ulcerative colitis or Crohn's disease
- Gallstone disease
- Pregnant women

Location:

San Francisco General Hospital GI Clinic
Joanne Seinsheimer
(415) 206-4746

85. Diarrhea Treatment: Questran, ADEK

Title:

H7531-12449-01: A Study Evaluating Bile Acid Malabsorption and Small Bowel Overgrowth in HIV-Associated Diarrhea

Type of treatment:

ADEK: vitamins
Questran: cholesterol lowering agent

Purpose:

To see if cholestyramine (Questran) is effective in controlling HIV-related diarrhea cause by bile acid malabsorption and/or an overgrowth of bacteria in the small bowel.

About the study:

Patients entering this study must have diarrhea that is not caused by any treatable organism. All patients will have an endoscopy, which is a small tube inserted into the throat to examine the upper digestive tract and to have a sample of fluid removed from part of the small intestine. Patients will also have a sigmoidoscopy, which is a tube inserted into the rectum to examine the lower intestinal tract. All patients will also have a breath study to see if they have bile acid malabsoprtion. After completing all these tests, patients will follow a diet of 100 grams of fat per day. During this period, patients will record all bowel movements during seven consecutive days. On days 4 to 7, they will collect all bowel movements in a container provided for this purpose and, at the end of the seven-day period, will bring in the collected stool for analysis. Patients will then take Questran (cholestyramine) for seven days. Questran is a powder which is mixed with water and taken orally. Patients will take Questran three times a day just before meals. Patients will follow the same diet and stool collec-

tion as before. Patients will also take one tablet of ADEK, a mulitvitamin containing Vitamins A, D, E, and K to prevent malnutrition. Study visits are once a week and the study lasts 6 - 8 weeks.

Required:

- CD4 cell (T-cell) range: not specified
- Viral load range: not specified
- At least 18 years old
- HIV positive
- HIV-associated diarrhea for which an endoscopic evaluation is considered necessary.
- Positive testing for fecal fat

Not allowed:

- Diarrhea caused by known treatable pathogens, such as parasites, amoebas
- Current active opportunistic infections requiring systemic treatment. Oral candidiasis (thrush) and KS are allowed.

Location:

Division of Gastroenterology at SFGH
Johannes Koch, MD
(415) 206-4753

86. Diarrhea Treatment: Chinese Herbs

Title:

CC 027: A Pilot Study of Chinese Herbs in HIV-Associated Pathogen-Negative Diarrhea

Type of treatment:

Chinese Herbs: Chinese Medicine

Purpose:

To see if taking a Chinese herbal medication is safe and effective in reducing the number of stools per day related to HIV-associated cryptosporidium-negative diarrhea.

About the study:

Patients will receive a Chinese herbal medication called Source Qi. Source Qi is a tablet and taken by mouth. Patients will take a minimum of 12 up to a maximum of 20 tablets a day. The study lasts eight weeks. Study visits will be conducted at baseline, and at weeks 2, 4, and 8 for evaluation of symptoms and side effects. Blood tests will be done at weeks 4 and 8. Stool samples will be collected at the beginning of the study. Patients will be required to keep a daily stool diary.

Required:

- CD4 cell (T-cell) range: not specified
- At least 17 years old
- HIV positive
- Chronic diarrhea defined as three or more loose stools per day for at least 14 days
- Baseline stool sample negative for treatable parasites including cryptosporidium

Not allowed:

- Any hospital admission within a month prior to study entry
- Documented allergies to Chinese herbs
- Stools containing blood which can be seen by the patient
- Fevers above 101F for greater than seven days
- Alternating constipation/diarrhea
- Any history of a cryptosporidium-positive stool

Location:

Community Consortium
To be arranged through physician - see page 119
(415) 476-9554

Quan Yin Healing Arts Center
Carla Wilson
(415) 861-4964

87. Cryptosporidiosis Treatment: Nitazoxanide

Title:

ACTG 336: A Phase II/III Placebo-Controlled Study of Nitazoxanide for Persons with AIDS and Cryptosporidiosis

Type of treatment:

Nitazoxanide: antiparasitic

Purpose:

To see if nitazoxanide (NTZ) is an effective treatment for cryptosporidiosis, a parasite that infects the intestines of people.

About the study:

Patients are assigned by chance to receive NTZ or placebo for three weeks. Neither patients nor their doctors will know which they are receiving until the study ends. At three weeks, all patients will receive NTZ for another three weeks. At six weeks, patients whose diarrhea has improved will be assigned by chance to receive a lower or higher dose of NTZ. Patients whose diarrhea has not improved or gets worse may receive a higher dose of NTZ. NTZ is taken by mouth. Study visits are once a week for the first month, then approximately once a month. The study lasts approximately eight months.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 13 years old
- Intestinal cryptosporidiosis with diarrhea producing at least four stools per day for at least 21 of the last 28 days

Not allowed:

- Patients unable to tolerate oral medications
- Diarrhea due to any other treatable cause

- Any additions or changes to antiretroviral medications within four weeks of study entry
- Prior use of nitazoxanide
- Women who are pregnant or breastfeeding

Location:

LAC-USC Medical Center
Frances Canchola, RN
(213) 343-8281

UCSF AIDS Program at SFGH/ACTU
Kathy Dybeck, RN
(415) 476-9296 ext. 353

88. HIV-Related Upper Gastrointestinal Symptoms: Metoclopramide

Title:

Metoclopramide for Stasis Dyspepsia in Patients Infected with the Human Immunodeficiency Virus: A Randomized, Double-Blind, Placebo-Controlled Trial

Type of treatment:

Metoclopramide: antinausea/vomiting

Purpose:

To see if metoclopramide (also called Reglan) is safe and effective in relieving upper gastrointestinal symptoms.

About the study:

Patients are assigned by chance to receive metoclopramide or placebo. Both metoclopramide and its placebo are pills and patients will take one pill three times a day for four weeks. Neither patients nor their doctors will know which they are receiving until the study ends. Before taking any medication, patients will be required to fill out a questionnaire asking them about their symptoms and how they affect their lives. Patients will also receive a gastric emptying study as well as an abdominal ultrasound exam to determine the rate at which the stomach empties its contents. After patients have started taking treatment, another gastric emptying study and abdominal ultrasound wil be performed. Study visits are once a week and the study lasts one month.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Symptoms of stasis dyspepsia such as: nausea or vomiting; upper abdominal pain; early satiety; unexplained weight loss with anorexia
- Patients are scheduled for or have undergone a routine gastric emptying study

Not allowed:

- Symptoms due to other causes such as active peptic ulcer disease, untreated CMV enteritis, diabetes mellitus or gastric outlet obstruction
- Patients who have had all or part of their stomach surgically removed

Location:

Division of Gastroenterology at SFGH
Douglas Corley, MD
(415) 206-8823

New

89. Chronic Hepatitis B Treatment: Lobucavir

Title:

A1459-008: A Pilot Randomized, Double-Blind Safety , Efficacy and Pharmacokinetics Study of Oral Lobucavir Compared to Placebo in Patients Chronically Infected with Hepatitis B Virus (HBV)

Type of treatment:

Lobucavir: antiviral

Purpose:

To see if lobucavir is safe and effective in reducing the amount of hepatitis virus in the blood. To see how lobucavir is processed by the body.

About the study:

There are two parts of this study. In Part A, patients are assigned by chance to receive one of two doses of lobucavir or placebo for 28 days. Neither patients nor their doctors will know which they are receiving until the study ends. There will be a 10-hour study period on the first day of medication dosing and another 10-hour visit during the third week. Study visits will be once a week. After 28 days, Part B will begin and patients are assigned by chance to receive one of three doses of lobucavir or placebo for the next three months. Study visits in Part B are once a week for the first month, then every two weeks until the end of the study. The study lasts 6 months.

Required:

- CD4 cell (T-cell) range: at least 300 (if HIV-positive)
- HIV status: positive or negative
- At least 18 years old
- Hepatitis viral load: more than 300 pg/mL
- Documented presence of hepatitis B antigen for 6 months

Not allowed:

- Positive antibodies for Hepatitis C or D
- Other forms of liver disease, such as Hepatitis A or chemical/alcoholic hepatitis
- Any pancreatitis within the past 6 months
- Currently taking 3TC or ddI
- Previous treatment with lobucavir
- Current alcohol or substance abuse
- Women who are pregnant or breastfeeding

- Use of any immunomodulators, such as interferons, interleukins or steroids within six months of study entry

Location:

ViRx, Inc.
Debbie Hildebrandt
(415) 353-5623

90. Histoplasmosis Treatment: AmBisome, Amphotericin B

Title:

A Phase IIB Study to Compare the Safety and Efficacy of AmBisome with Conventional Amphotericin B for Induction Therapy of Histoplasmosis in Patients with AIDS

Type of treatment:

AmBisome: antifungal
Amphotericin B: antifungal

Purpose:

To see if the new liposomal formulation of amphotericin B is safer and more effective than the older formulation in treating moderate to severe histoplasmosis. AmBisome is Amphotericin B that has been packaged in fat molecules, which makes higher doses easier to tolerate.

About the study:

Patients will be assigned by chance to receive AmBisome or Amphotericin B. Both medications are given as an infusion into a vein. Neither patients nor their doctors will know which they are taking until the study ends. Patients will receive study medication for two weeks. After the two weeks of induction therapy, all patients will then take oral itraconazole daily for ten weeks. The study lasts 12 weeks. Induction therapy can be stopped after a minimum of seven days for those patients who respond well to treatment.

Required:

- CD4 cell (T-cell) range: not specified,
- HIV positive
- At least 18 years old
- Evidence of disseminated histoplasmosis

Not allowed:

- Known allergy to amphotericin B
- Any other active opportunistic infection
- Pregnant or nursing women

Location:

UCSF AIDS Program at SFGH/ICTG
Nelson Murcar, RN
(415) 476-9296, ext. 333

91. Herpes Simplex (perianal) Treatment:Virend 15%, Acyclovir

Title:

SP303T-A-04: Double-Blind, Placebo-Controlled Study to Compare the Combination of Virend 15% Gel with Acyclovir versus Acyclovir Alone for the Treatment of Recurrent Herpes Simplex Virus (HSV) Infections in Subjects with Acquired Immunodeficiency Syndrome

Type of treatment:

Virend 15%: antiviral topical gel
Acyclovir: antiviral

Purpose:

To compare the effectiveness of Virend 15% topical gel in combination with acyclovir to acyclovir alone for the treatment of anogenital herpes simplex infections.

About the study:

Patients are assigned by chance to receive Virend 15% topical gel or placebo gel to take with oral acyclovir. Neither patients nor their doctors will know which they are receiving until the study ends. All patients will take acyclovir. Acyclovir is a pill and taken by mouth. Virend 15% and its placebo are gels which are applied to herpes lesions. Study visits are approximately every other day for the first two weeks with a final study visit at week 4. The study lasts 28 days.

Required:

- CD4 cell (T-cell) range: not applicable
- At least 18 years old
- HIV positive
- Documented recurrent (at least one prior episode) of perineal (genital, perianal and neighboring areas) herpes simplex virus infection
- Current infection must be less than 3 days old at study entry
- Stable antiretroviral therapy (if any) for at least the past two weeks prior to study entry

Not allowed:

- Prior episode of herpes simplex which failed acyclovir treatment
- Treatment with any other anti-herpes medication within the past five days prior to study entry
- Active internal or rectal herpes
- Women who are pregnant or breastfeeding
- Use of any immunomodulators within 30 days prior to study entry
- Previous use of Virend 15%

Location:

ViRx, Inc.
Debbie Hildebrandt
(415) 353-5623

Summit Medical Center Adult Immunology Clinic
Jamie Carroll, RN
(510) 869-6514

Marcus Conant, MD Clinical Research
Michael Feist
(415) 661-2613

ViRx, Inc. - Palm Springs
Val Crotty
(760) 864-6266

92. Herpes Simplex: Observational

Title:

Multisite Antiviral Resistance Studies Pilot Surveillance for Acyclovir-Resistant HSVII

Type of treatment:

Observational: none

Purpose:

To determine the extent of acyclovir-resistant herpes simplex. To collect and store specimens of acyclovir-resistant genital herpes simplex for in-depth lab studies.

About the study:

Patients joining this study will have one study visit where a herpes swab will be taken and patients will fill out a questionnaire. This study is limited to patients who have peri-anal or rectal herpes.

Required:

- Herpes simplex lesion in the peri-anal or rectal area

Not allowed:

- No exclusions

Location:

San Francisco VA Medical Center
Sandy Charles, RN
(415) 221-4810, ext. 3763

93. KS Treatment: Tin Ethyl Etiopurpurin

Title:

PDTP-920101-CA007: A Phase II/III Open Label, Randomized, Controlled Study of Single Dose Tin Ethyl Etiopurpurin Photodynamic Therapy in the Treatment of AIDS-Associated Kaposi's Sarcoma

Type of treatment:

Tin Ethyl Etiopurpurin: anti-KS

Purpose:

To see if Tin Ethyl Etiopurpurin combined with a laser light beam is an effective way to treat KS lesions.

About the study:

All patients receive Tin Ethyl Etiopurpurin. Patients are assigned by chance to receive laser light treatment or no light treatment for selected KS lesions. Tin Ethyl Etiopurpurin is given by infusion into a vein and lasts about 90 minutes. There is only one infusion at the beginning of the study. The study lasts for six months and requires five study visits. Patients will be paid for completing the study.

Required:

- CD4 cell (T-cell) range: not specified
- Kaposi's Sarcoma of the skin with at least four lesions
- At least 18 years old

Not allowed:

- Greater than 36 KS lesions
- Pregnant or nursing women
- Active opportunistic infections except thrush or herpes infections
- Cirrhosis requiring current treatment
- KS that has spread to internal organs
- Known sensitivity to light, egg proteins and yolks
- History of lupus erythematosus
- Systemic chemotherapy or interferon in the last 30 days
- Local cryotherapy, intralesional chemotherapy or surgery to study lesions within the past 12 weeks

Location:

UCSF/SFGH Dermatology
Carole Benson, RN
(415) 476-4256

94. KS Treatment: Topotecan

Title:

SKF 104864-4: An Open, Non-Comparative, Phase II Study of Topotecan, Given as a 30-Minute Infusion on Five Consecutive Days Every 21 Days, to Patients with Kaposi's Sarcoma

Type of treatment:

Topotecan: chemotherapy, systemic

Purpose:

To learn whether and how quickly AIDS-related KS gets better with treatment with Topotecan.

About the study:

All patients receive treatment with Topotecan. Topotecan is given as an infusion into a vein, and participants will need to have a "PIC line" inserted. A PIC line is a small tube (catheter) semi-permanently inserted into a vein in the arm. Treatments are given through this tube at home for 30 minutes on five consecutive days every 21 days. All participants go through at least two 21-day cycles, given 4 weeks apart. Patients must come to the clinic weekly to get more drug to infuse at home.

Required:

- CD4 cell (T-cell) range: above 50
- HIV positive
- At least 18 years old
- KS that got worse after treatment with at least 2 different kinds of chemotherapy
- At least 3-5 KS lesions that can be measured

Not allowed:

- More than 2 prior chemotherapy regimens
- KS that has spread to the lungs
- Extensive radiation within last 2 weeks

- Serious opportunistic infection requiring acute therapy (long term MAC treatment is allowed)
- Pregnant or breastfeeding women

Location:

AIDS Oncology Practice at UCSF / Mt. Zion
Barbara Klencke, MD
(415) 567-5581

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

UCSF AIDS Program at SFGH/ICTG
Dorie Heeren, RN
(415) 476-9296, ext. 305

95. KS Treatment: Liarozole

Title:

LIA-USA-34: A Pilot, Phase II Study of Liarozole in Kaposi's Sarcoma

Type of treatment:

Liarozole: chemotherapy

Purpose:

To see if the new drug, liarozole is a safe and effective treatment for KS lesions.

About the study:

This is a dose-escalating study. This means that the first ten patients to enroll on the study will take 150 mg of liarozole twice a day. The second ten patients to enroll will take 150 mg of liarozole twice a day for two weeks, then take 300 mg of liarozole twice a day. Liarozole is a pill and is taken by mouth. Treatment will last 48 weeks and study follow-up will last for six months.

Required:

- CD4 cell (T-cell) range: 50 or more
- HIV positive
- At least 18 years old
- Biopsy-proven KS skin lesions and at least one lesion that has not been treated with local therapy

Not allowed:

- Pulmonary KS
- Female patients
- Ongoing therapy for infections (preventive medicine for PCP or MAC is allowed)
- Active infections
- Other cancers
- Use of chemotherapy, radiation or immune modulators within 30 days of study entry
- Active substance abuse

Location:

AIDS Oncology Practice at UCSF / Mt. Zion
Barbara Klencke, MD
(415) 567-5581

UCSF AIDS Program at SFGH/ICTG
Dorie Heeren, RN
(415) 476-9296, ext. 305

AIDS Community Research Consortium
Mari Steeno, RN
(650) 364-6563

96. KS Treatment: Paclitaxel

Title:

1X-110-081: Paclitaxel in Advanced Refractory Kaposi's Sarcoma: A Phase II Trial of Paclitaxel from Baker Norton Pharmaceuticals

Type of treatment:

Paclitaxel: chemotherapy

Purpose:

To see if paclitaxel is safe and effective in treating advanced KS lesions.

About the study:

All patients will receive paclitaxel every two weeks. Paclitaxel is given by infusion into a vein. Infusions last about three hours. The study will last 20 weeks.

Required:

- CD4 cell (T-cell) range: not specified
- Advanced KS lesions, defined as: at least 25 or more skin lesions; internal organ involvement; symptomatic edema (swelling)
- At least 18 years old
- Must have had at least one systemic chemotherapy treatment which failed to provide any benefit

Not allowed:

- Systemic chemotherapy within two weeks of study entry
- Women who are pregnant or breastfeeding
- Other cancers
- Current serious infections
- Any chest pains or heart attack in the past six months
- Any prior use of Paclitaxel

Location:

UCSD Treatment Center
Anne French, RN
(619) 543-8080 ext. 238

LAC-USC Medical Center
Suzanne Cabriales, RN
(213) 343-8270

97. KS Treatment: LGD1069 (Targretin)

Title:

L1069-21: A Phase II Evaluation of Targretin Capsules in Patients with AIDS-Related Kaposi's Sarcoma

Type of treatment:

LGD 1069 (Targretin): anti-KS

Purpose:

To see if LGD1069 (also called Targretin) is safe and well tolerated and to see if it is effective in treating KS lesions in AIDS patients.

About the study:

All patients will receive Targretin. There are no placebos in this study. Targretin is a capsule taken by mouth once a day. The dose of Targretin may be lowered depending on any toxic side effects patients may experience. Study visits are every two weeks and the study lasts for 16 weeks. If the study remains open and active, patients may continue treatment for as long as the treatment is considered to be of clinical benefit and has not shown severe side effects.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- At least 18 years old
- Diagnosis of KS proven by biopsy. Patients must have a minimum of six lesions, three of which are raised, and have been present for at least 30 days or measure at least 1.0 cm.
- Must have been on stable antiretroviral therapy for at least six weeks prior, during, and at least one month after drug discontinuation

Not allowed:

- Women who are pregnant or breastfeeding
- Systemic treatment for KS within 30 days of study entry
- Systemic treatment with Vitamin A (more than 15,000 IU per day) or other retinoid class drugs within 30 days of study entry
- Previous treatment of study lesions with any local or topical therapy within 60 days of study entry
- Concurrent serious, uncontrolled infections such as MAC, PCP, CMV, toxoplasmosis or meningitis
- Any known allergy to retinoid class drugs
- Concurrent treatment with local or topical therapy such as Vitamin A, cryotherapy, radiation therapy, intralesional injection or photodynamic therapy for any study lesion

Location:

Desert Hospital Comprehensive Cancer Center
Elizabeth Wilson, RN
(760) 416-4733

Marcus Conant, MD Clinical Research
Michael Feist
(415) 661-2613

98. KS Treatment: IM-862

Title:

17K-96-3: IM-862 Product Nasal Solution Open Label Investigator Protocol for Evaluation of IM-862 Treatment in Kaposi's Sarcoma Subjects

Type of treatment:

IM-862: immune modulator

Purpose:

To see if the new drug IM-862 is safe and effective in treating KS lesions

About the study:

Patients are assigned by chance to receive one of two treatment schedules using IM-862. IM-862 is a nasal solution and applied to the nose much like nose drops. One group will take IM-862 every other day for 90 days. The other group will take IM-862 for five consecutive days followed by five days of rest. They will repeat this cycle for 90 days. All patients will be taking IM-862. There are no placebos. Study visits are every two weeks and the study lasts 90 days. Patients will have two skin biopsies on a KS lesion during the study.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: not applicable
- HIV positive
- At least 18 years old
- Biopsy-proven diagnosis of KS of the skin with at least five lesions involving the skin or oral cavity

Not allowed:

- Any AIDS-defining opportunistic infections
- Use of steroids within 14 days of study entry
- Use of interferons, interleukins or chemotherapy within three weeks of study entry
- Radiation therapy within four weeks of study entry
- Previous use of IM-862
- Women who are pregnant or breastfeeding
- Past or current other cancer excluding basal cell skin cancer or cervical cancer
- Active drug or alcohol abuse

Location:

LAC-USC Medical Center
Suzanne Cabriales, RN
(213) 343-8270

99. KS Treatment: Radiation

Title:

UCD95KS001: A Prospective, Randomized Controlled Trial of Radiation Therapy for Early Stage AIDS-Associated Kaposi's Sarcoma

Type of treatment:

Radiation:

Purpose:

To see which dose of radiation is best for treating localized KS lesions.

About the study:

Patients entering this study must have at least two KS lesions that could benefit from therapy. Two lesions will be treated with different doses of radiation. One lesion will receive a lower dose once. The other lesion will receive a higher dose every day for ten days. Patients will come to the clinic everyday for two weeks during radiation treatment. Follow-up visits are at one

month, then every two months until progression of the treated lesions. The study lasts indefinitely.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- At least two, biopsy-proven KS lesions of the skin

Not allowed:

- Any other cancers in the past five years, except non-melanoma skin cancer
- KS of the internal organs

Location:

UC Davis Cancer Center
Cheri Koppe
(916) 734-3604

100. KS Treatment: TNF Receptors

Title:

Phase II Study of Soluble TNF Receptors in Patients with AIDS and Kaposi's Sarcoma

Type of treatment:

TNF Receptors: immune modulator

Purpose:

To see if soluble TNF receptors are safe and to see what effect they have on tumor growth.

About the study:

All patients in this study will receive soluble TNF receptors. TNF is given by injection under the skin. Patients will receive injections twice a week for 12 weeks. Because immunme modulators such as TNF can activate HIV, all patients must take some form of antiretroviral therapy.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 12 years old
- Biopsy-proven KS
- Must be taking some form of antiretroviral therapy

Not allowed:

- Greater than 50 KS lesions on the skin and/or KS of the internal organs
- Any other cancers except cervical or basal cell
- Women who are pregnant or breastfeeding
- Patients with more than 200 T-cells must never have had an opportunistic infection; patients with less than 200 T-cells may not have an uncontrolled concurrent opportunistic infection
- Prior cardiac disease
- Use of immunomodulators, interferons, Megace or Trentol within four weeks of study entry

Location:

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

101. KS Treatment: Piritrexim

Title:

A Phase III Trial to Determine the Effect of Piritrexim on the Rate of Formation of New KS Lesions

Type of treatment:

Piritrexim: antitumor agent

Purpose:

To evaluate the ability of the oral drug piritrexim to control early KS. To determine the side effects and response to piritrexim.

About the study:

Patients are assigned by chance to receive piritrexim or placebo. Neither patients nor their doctors will know which they are receiving until the study ends. Patients will take piritrexim or placebo three times a day, five days a week for three weeks; followed by one week without taking any drug or placebo. Treatment will continue until evidence of KS progression. Patients who are receiving placebo will receive open-label (real) piritrexim if they demonstrate progression of KS lesions. Study visits are once a month.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Biopsy-proven KS with between 5 and 25 skin lesions

Not allowed:

- KS that has spread to internal organs
- Any prior cancers
- Prior treatment with chemotherapy
- Women who are pregnant or breastfeeding
- Active serious illnesses or infections

Location:

LAC-USC Medical Center
Suzanne Cabriales, RN
(213) 343-8270

102. KS Treatment: Alpha Interferon, Ritonavir, d4T

Title:

AMC004: Ritonavir Combined with Interferon alpha-2b and Stavudine in Patients with AIDS-Related Kaposi's Sarcoma

Type of treatment:

Ritonavir: antiretroviral, protease inhibitor
Interferon, alpha: immune modulator
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see if interferon alpha-2b is safe and well tolerated when combined with ritonavir (also called Norvir) and stavudine (also called d4T). To see what effect this combination has on tumor response, CD4 and CD8 cells, and to see how these drugs interact and are processed by the body.

About the study:

Patients are assigned by chance to receive ritonavir, d4T plus alpha interferon or to receive ritonavir and d4T. Patients will know which medications they are taking. Those patients assigned to receive alpha interferon will receive the lowest dose, then increasing doses if alpha interferon is well tolerated. Alpha interferon is given by injection under the skin and patients will be taught how to give themselves injections at home if they wish. Injections are given once a day. Study visits are every two weeks for the first eight weeks, then once a month. The study lasts indefinitely.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 13 years old
- Biopsy-confirmed cutaneous KS with at least three lesions
- All other antiretroviral therapy, other than d4T, must be discontinued for at least 14 days before study entry

Not allowed:

- Current acute opportunistic infections
- KS that has spread to the internal organs
- Any other cancers other than basal cell carcinoma or ano-genital neoplasia
- Acute or chronic pancreatitis within two years of study entry
- Severe peripheral neuropathy within four months of study entry
- Prior use of systemic alpha interferon, ritonavir or indinavir
- Use of chemotherapy, radiation, corticosteroids, rifampin or rifabutin within 14 days of study entry

Location:

AIDS Oncology Practice at UCSF / Mt. Zion
Barbara Klencke, MD
(415) 567-5581

UC Davis Cancer Center
Cheri Koppe
(916) 734-3604

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

UCSF AIDS Program at SFGH/ICTG
Sean Carnahan
(415) 476-9296 ext. 301

103. KS Treatment: Amifostine, Taxol

Title:

An Open Randomized Comparison Trial of Cytoprotective Effects of Amifostine in HIV Infected Individuals Undergoing Systemic Chemotherapy for AIDS-Related Kaposi's Sarcoma

Type of treatment:

Amifostine: anti-neutropenia
Paclitaxel: chemotherapy

Purpose:

To see if it is safe and effective to use amifostine to reduce the chance of having low white blood cell counts for patients who are being treated with Taxol for KS.

About the study:

Patients are assigned by chance to receive amifostine before receiving Taxol or to receive Taxol alone. Patients will know which they are receiving. Both amifostine and Taxol are given by infusion into a vein. Patients assigned to receive amifostine will be infused one half hour before Taxol infusion. Infusions are given every two weeks. The maximum number of infusions in this study is six. KS lesions will be evaulated prior to each infusion and four weeks after the last infusion.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Biopsy-proven KS

Not allowed:

- Use of any investigational drug within 14 days of study entry
- Any acute active opportunistic infections
- Other cancers, except basal or squamous cell of the skin or cervical cancer
- CMV infection requiring treatment with ganciclovir
- Use of GM-CSF or G-CSF throughout the study
- Women who are pregnant or breastfeeding

Location:

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

104. KS Treatment: Viracept (nelfinavir)

Title:

AG1343-513: A Pilot, Open-Label, Phase II, Randomized, Study to Determine the Effects of Viracept on the Outcome of Cutaneous and Mucosal KS in AIDS Patients of 500 cells/mm^3 or Less

Type of treatment:

Nelfinavir: antiretroviral, protease inhibitor

Purpose:

To determine the effect of Viracept in combination with other antiretroviral therapy on skin and mucosal KS lesions in patients with HIV infection.

About the study:

Patients are assigned by chance to receive Viracept to take in addition to their antiretroviral therapy or to continue on their antiretroviral therapy without Viracept. Patients will have photographs taken of their KS lesions at the beginning of and throughout the study. After eight weeks, all patients will take Viracept in addition to their antiretroviral medications. Study visits are once a month and the study lasts at least three months.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 13 years old
- Biopsy-proven KS with at least four skin lesions not previously treated

Not allowed:

- Prior use of Viracept (nelfinavir)
- Women who are pregnant or breastfeeding

Location:

UCSD Treatment Center
Anne French, RN
(619) 543-8080 ext. 238

105. KS Treatment: Piritrexim (2)

Title:

PTX-002: A Phase II Open Label Trial of Piritrexim in Patients with Cutaneous Kaposi's Sarcoma who Failed Placebo on PTX 001-96

Type of treatment:

Piritrexim: antitumor agent

Purpose:

To see if piritrexim is safe and effective for patients with KS lesions of the skin who were assigned to take placebo on the PTX-001 study.

About the study:

All patients will receive piritrexim during the study. Piritrexim is a pill and is taken three times a day for five consecutive days per week for three weeks. Patients will not take any medication during the fourth week. After the fourth week, the treatment cycle will begin again. Study visits are every week for the first month, then once a month. Patients' KS lesions will be evaluated at each study visit. The study lasts indefinitely.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Patients who received a placebo on the PTX-001 piritrexim study
- Confirmed diagnosis of KS with a maximum of 50 lesions

Not allowed:

- KS of the internal organs
- Women who are pregnant or breastfeeding
- Prior chemotherapy for KS treatment
- Any other cancers except cervical or non-melanoma skin cancer

Location:

LAC-USC Medical Center
Suzanne Cabriales, RN
(213) 343-8270

106. KS Treatment: ALRT1057 Oral Capsules

Title:

AMC002: A Phase II Evaluation of Oral ALRT1057 in Patients with AIDS-Related Kaposi's Sarcoma

Type of treatment:

ALRT1057: anti-KS

Purpose:

To see if oral ALRT1057 (also called PANRETIN or 9-cis retinoic acid) is safe and well tolerated and to see if it is effective in treating KS lesions in AIDS patients.

About the study:

This is a dose-escalation or dose-ranging study. This means that patients will enter the study taking the lowest dose of oral ALRT1057. The dose will gradually be increased over time until the maximum dose that researchers plan to study has been given. All patients will receive oral ALRT1057. There are no placebos in this study. Oral ALRT1057 is a capsule and taken once a day. Study visits are every two weeks and the study lasts 16 weeks. If the study remains open and active, patients may continue treatment for as long as the treatment is considered to be of clinical benefit and has not shown severe side effects.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Diagnosis of KS proven by biopsy. Patients must have a minimum of six skin lesions, three of which are raised, and have been present for at least 30 days or measure at least 1.0 cm
- Must have been on approved antiretroviral therapy for at least six weeks prior, during, and at least one month after drug discontinuation

Not allowed:

- Women who are pregnant or breastfeeding
- Systemic treatment for KS within 30 days of study entry
- Systemic treatment with Vitamin A (more than 15,000 IU per day) or other retinoid class drugs within 30 days of study entry
- Previous treatment of study (indicator) lesions with any local or topical therapy within 60 days of study entry
- Current serious illness or infection which would interfere with the ability of the patient to carry out the treatment program
- Any known allergy to retinoid class drugs
- Concurrent treatment with local or topical therapy such as Vitamin A, cryotherapy, radiation therapy, intralesional injection or photodynamic therapy for any indicator lesion

Location:

AIDS Oncology Practice at UCSF / Mt. Zion
Barbara Klencke, MD
(415) 567-5581

UC Davis Cancer Center
Cheri Koppe
(916) 734-3604

UCSF AIDS Program at SFGH/ICTG
Sean Carnahan
(415) 476-9296 ext. 301

LAC-USC Medical Center
Suzanne Cabriales, RN
(213) 343-8270

107. KS Treatment: Toremifine

Title:

UCD 97KS-002: Clinical Pilot Study of Toremifine for the Treatment of AIDS-Associated Kaposi's Sarcoma

Type of treatment:

Toremifene: anti-tumor

Purpose:

To see if the new drug toremifine is safe and effective in slowing the growth of KS tumor cells. To see what effect toremifine has on T-cell counts and HIV viral load.

About the study:

This is a dose-escalation or dose-ranging study. This means that the toremifine dose will be gradually increased for each patient until the highest dose researchers plan to study has been given or the highest dose that patients can tolerate with no bad side effects has been found. Toremifine is a pill and taken by mouth once a day before breakfast. Patients will be on study medication for at least 16 weeks. After 16 weeks, patients may continue to take torefimine for up to one year if the patient's physician feels that the treatment is of benefit. Study visits are once a month and the study lasts up to one year.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Biopsy-proven KS of the skin with at least five lesions that have not been treated with local or topical therapy within 60 days
- Must be on stable (no changes) antiretroviral therapy for at least four weeks prior to study entry

Not allowed:

- KS that has spread to the internal organs
- Any other cancers except basal cell of the skin or cervical cancer
- Prior chemotherapy for KS within four weeks of study entry
- Women who are pregnant or breastfeeding

Location:

UC Davis Cancer Center
Cheri Koppe
(916) 734-3604

New

108. KS Treatment: 9-aminocamptothecin (9-AC/DMA)

Title:

AMC006: Phase II Study of 9-aminocamptothecin (9-AC/DMA) in Patients with AIDS-Related Kaposi's Sarcoma

Type of treatment:

9-aminocamptothecin: anti-tumor drug

Purpose:

To see if 9-aminocamptothecin is safe and effective in treating KS lesions. To see what effect 9-aminocomptothecin has on HIV infection.

About the study:

All patients will receive 9-aminocaptothecin through a central line, a tube placed surgically into a large vein located near the collar bone, continuously over a period of 72 hours (3 days). This 72-hour period is called a cycle, and cycles will be repeated every two weeks. Patients will need to stay in the hospital for the first 72-hour infusion. Patients will have blood tests every week and will be evaulated after each treatment cycle. Patients may

continue receiving treatment as long as their physician feels that their KS is responding to the treatment. The study lasts about two years.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Patients may have received up to three chemotherapy drugs if discontinued more than two weeks prior to study entry
- Biopsy-proven, untreated KS lesions of the skin

Not allowed:

- Active, untreated opportunistic infections
- More than seven days of radiation treatment to non-study lesions. Study lesions must not have received any radiation
- Use of G-CSF or GM-CSF within two weeks of study entry
- Use of any investigational drug within two weeks prior to study entry
- Any cancers other than treated cervical cancer or basal/squamous cell cancer of the skin
- Women who are pregnant or breastfeeding

Location:

LAC-USC Medical Center - Norris Cancer Hospital
Byron Espina
(213) 764-0371

109. KS: Observational

Title:

BRL-002: The Establishment of Kaposi's Cell Lines From Volunteer Patient Punch Biopsy Specimens

Type of treatment:

None: observational, natural history

Purpose:

To collect KS lesion cells to be grown in the laboratory and used to measure response to radiation and other possible treatments.

About the study:

Patients will have some tissue removed from one of their KS lesions. The site will be cleaned and numbed and a small piece of KS lesion will be removed by a small incision. Patients will receive a single stitch and dressing and be asked to return in one week to have the stitch removed and the site inspected for any sign of infection. Patients will receive a check for $25 within one month of the procedure for participating in this project. Patients will be required to give their name, address and Social Security number.

Required:

- KS of the skin

Not allowed:

- No exclusions

Location:

UC Davis Cancer Center
Cheri Koppe
(916) 734-3604

110. Non-Hodgkin's Lymphoma Treatment: Gallium Nitrate

Title:

A Phase II Evaluation of Gallium Nitrate (NSC 15200) in Non-Hodgkin's Lymphoma Associated with AIDS

Type of treatment:

Gallium Nitrate: anti-cancer

Purpose:

To see how quickly and how long patients respond to treatment with gallium nitrate after they have failed treatment with chemotherapy drugs. To see what side effects gallium nitrate may cause.

About the study:

All patients will receive gallium nitrate. Gallium nitrate is given by injection into a vein (infusion). Infusions are given every day for seven days and repeated every three weeks. Patients who experience complete remission will receive two additional treatments. If patients relapse, they may restart the treatment program. The study will last indefinitely.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- Diagnosis of non-Hodgkin's lymphoma
- Patients must have failed one potentially curative treatment for lymphoma
- A lumbar puncture (spinal tap) will be performed at the beginning of the study

Not allowed:

- CNS lymphoma
- Any other cancer except cervical, basal cell of the skin or KS of the skin and not requiring chemotherapy
- Any severe, acute opportunistic infection
- Current radiation therapy or other chemotherapy
- Women who are pregnant or breastfeeding
- Significant cardiovascular disease, such as recent heart attack, past congestive heart failure, angina, or serious arrythmias

Location:

LAC-USC Medical Center - Norris Cancer Hospital
Joanne Shifflett, RN
(213) 226-4578

III. AIDS-Related Lymphoma Treatment: Chemotherapy

Title:

A Phase II, Open-Label Study of Infusional Chemotherapy in the Treatment of AIDS-Related Lymphoma

Type of treatment:

Chemotherapy, systemic: chemotherapy

Purpose:

To see how long it takes for lymphoma to respond to the treatment and how long the response lasts; to see how safe this treatment is and what side effects it has.

About the study:

All patients will receive a combination of cyclophosphamide, mitoxantrone and etoposide. These drugs are given as an infusion into a vein. Patients will need to have a central line. A central line is a tube inserted into a vein in the chest area and involves minor surgery. Infusions will take place every three to four weeks. Patients will be in this study for four to six months.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- At least 17 years old
- A diagnosis of B-cell immunoblastic lymphoma, small non-cleaved (either Burkitt or Burkitt-like) lymphoma, large non-cleaved or large-cleaved lymphoma

Not allowed:

- Any acute infection within two weeks of starting the study
- Any other cancer, other than KS or cervical cancer not requiring chemotherapy
- Primary CNS lymphoma
- Use of AZT during the study
- Past use of cytotoxic chemotherapy
- Any radiation therapy with four weeks of study entry
- Any immunomodulators within two weeks of study entry
- Women who are pregnant or breastfeeding

Location:

LAC-USC Medical Center - Norris Cancer Hospital
Joanne Shifflett, RN
(213) 226-4578

II2. Non-Hodgkin's Lymphoma Treatment: Mitoguazone (MGBG), CHOP Chemotherapy

Title:

A Phase II Study of Mitoguazone In Combination with CHOP Chemotherapy in Patients with Newly Diagnosed AIDS-Related Non-Hodgkin's Lymphoma

Type of treatment:

Mitoguazone dihydrochloride: chemotherapy
Chemotherapy, systemic: chemotherapy

Purpose:

To see if mitoguazone (MGBG) combined with CHOP chemotherapy (cyclophosphamide, adriamycin, vincristine, prednisone) is a safe and effective treatment for non-Hodgkin's lymphoma.

About the study:

All patients will receive mitoguazone and CHOP chemotherapy. CHOP chemotherapy consists of cyclophosphamide, adriamycin and vincristine given by infusion into a vein. Prednisone will be given orally on days 1-5. Mitoguazone will be given on days 1 and 15. CHOP chemotherapy will be given on day 1. This cycle is repeated every 28 days. Study visits are every two weeks and the study lasts four to six months. Patients will be evaluated by CAT scans, MRI or CT of the head, and a lumbar puncture (spinal tap) at the beginning of the study.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- At least 18 years old
- Newly diagnosed non-Hodgkin's lymphoma, not previously treated

Not allowed:

- Acute infections
- Other cancers except skin, cervical or KS that does not require systemic therapy
- CNS lymphoma
- Past use of cytotoxic chemotherapy
- Any radiation therapy within four weeks of study entry
- Any immunomodulators (interferons, interleukins) within two weeks of study entry
- Women who are pregnant or breastfeeding

Location:

LAC-USC Medical Center - Norris Cancer Hospital
Joanne Shifflett, RN
(213) 226-4578

II3. Non-Hodgkin's Lymphoma Treatment: PEG L-Asparaginase

Title:

17NHL-96-3: A Phase I Study of PEG L-asparaginase in the Treatment of Refractory/Relapsed AIDS-Related Non-Hodgkin's Lymphoma (AIDS-NHL)

Type of treatment:

L-Asparaginase:

Purpose:

To see if PEG L-Asparaginase is safe and to determine the maximum dose that is tolerated in patients who have relapsed NHL or are not responding to other treatment. To see how PEG L-asparaginase is processed by the body. To see what level of anti-tumor response PEG L-asparaginase has.

About the study:

This is a dose-ranging or dose-escalating study. This means that the first patients to enroll on the study will receive the lowest dose of PEG L-asparaginase. If this dose is found to be well-tolerated, the next group of patients will receive a higher dose. This procedure is followed until the highest dose of PEG L-asparaginase that researchers plan to study has been given OR the highest dose is found which does not cause bad side effects. PEG L-asparaginase is given by injection into a muscle. Patients will receive injections every two weeks until they develop intolerable side effects OR they have complete remission (disappearance of lymphoma) OR they choose to stop the treatment. Study visits are every two weeks and the study lasts at least one month. Patients will be required to have a lumbar puncture (spinal tap), CT scan of the head and bone marrow biopsy at the beginning of the study.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: not applicable
- HIV positive
- At least 17 years old
- Diagnosis of non-Hodgkin's lymphoma that has come back **OR** never gone away with prior exposure to any chemotherapy or radiation treatment

Not allowed:

- Acute intercurrent infection
- Patients with other cancers except basal cell carcinoma, cervical cancer, or KS of the skin, not requiring systemic chemotherapy
- CNS lymphoma
- Past or current pancreatitis
- Treatment with chemotherapy or radiation therapy within two weeks of study entry
- Prior use of L-asparaginase
- Women who are pregnant or breastfeeding

Location:

LAC-USC Medical Center - Norris Cancer Hospital
Laura Harvey-Buchanan, RN
(213) 226-4578

114. Non-Hodgkin's Lymphoma Treatment: DaunoXome

Title:

103-41: DaunoXome In the Treatment of HIV-Associated Refractory or Relapsed Non-Hodgkin's Lymphoma (Phase II)

Type of treatment:

DaunoXome: chemotherapy

Purpose:

To see if DaunoXome is safe and effective in treating non-Hodgkin's lymphoma in patients that have tried at least one other treatment with no response and/or for patients who have relapsed after treatment.

About the study:

All patients enrolling in this study will have tried at least one other potential treatment or have relapsed after using that treatment. All patients will receive DaunoXome. DaunoXome is given by infusion into a vein. Medication is given every three weeks. This study will last indefinitely. Patients are required to have a bone marrow biopsy for this study.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Confirmed diagnosis of intermediate or high grade non-Hodgkin's lymphoma
- Patients must have received at least one potential treatment for non-Hodgkin's lymphoma

Not allowed:

- Any chemotherapy, radiation or hormone therapy must have been discontinued for at least two weeks prior to enrollment
- Patients with CNS lymphoma
- Women who are pregnant or breastfeeding
- Any active AIDS-defining opportunistic infection within two weeks prior to enrollment, except herpes simplex or oropharangeal candidiasis (thrush)
- Cardiac conditions such as atrial arrhythmias, unstable angina, or myocardial infarction, congestive heart failure, coronary artery bypass or coronary angiopasty
- Any cancers other than skin, cervical, or KS of the skin

Location:

LAC-USC Medical Center - Norris Cancer Hospital
Byron Espina
(213) 764-0371

115. Epstein Barr-Associated Malignancies Treatment: 5-Azacytidine

Title:

AMC001/T93-0116: A Pilot Study of 5-Azacytidine Given as a 7-Day Continuous Infusion in HIV Patients with Relapsed and/or Refractory EBV-Associated Malignancies

Type of treatment:

5-Azacytidine:

Purpose:

To see if 5-azacytidine is a safe and effective treatment for patients with Epstein Barr-associated malignancies that have not gotten better with standard chemotherapy treatment.

About the study:

Patients will enter the hospital and receive 5-azacytidine for seven consecutive days. 5-azacytidine is given by infusion into a vein. All patients will receive 5-azacytidine. There are no placebos. Patients will receive one to three courses of treatment (infusion over one week every 28 days) depending on how well the treatment is tolerated and on how the tumor responds to treatment. The study lasts at least two months.

Required:

- CD4 cell (T-cell) range: not applicable
- At least 18 years old
- HIV positive
- Diagnosis of Hodgkin's or non-Hodgkin's lymphoma with Epstein Barr virus involvement

Not allowed:

- CNS cancers
- Women who are pregnant or breastfeeding
- Active, uncontrolled infections

Location:

AIDS Oncology Practice at UCSF / Mt. Zion
Barbara Klencke, MD
(415) 567-5581

LAC-USC Medical Center - Norris Cancer Hospital
Joanne Shifflett, RN
(213) 226-4578

UCSF AIDS Program at SFGH/ICTG
Nelson Murcar, RN
(415) 476-9296, ext. 333

116. AIDS-Associated Lymphoma Treatment: 90Y-Lym-I

Title:

UCD-RT0301: Immunotherapy of AIDS-Associated Lymphoma With 90Y-Lym-1

Type of treatment:

90Y-Lym-1: radiation therapy

Purpose:

To see if 90Y-Lym-1 is a safe and effective treatment for AIDS-associated lymphoma.

About the study:

All patients in this study will receive 90Y-Lym-1. 90Y-Lym-1 is given by infusion into a vein. Infusions are given every four weeks for 12 weeks. Patients will be in this study until their lymphoma progresses.

Required:

- CD4 cell (T-cell) range: at least 25
- HIV positive
- At least 18 years old
- Diagnosed with AIDS-associated lymphoma

Not allowed:

- Any other cancers within the last five years, except non-melanoma skin cancer and KS of the skin
- Women who are pregnant or breastfeeding

Location:

UC Davis Cancer Center
Cheri Koppe
(916) 734-3604

117. Non-Hodgkin's Lymphoma Treatment: CHOP, d4T, 3TC, Indinavir

Title:

AMC005: Pilot Study of the Effects of Combination Chemotherapy (modified CHOP) and Triple Antiretroviral Therapy on Outcome and Viral Load in the Treatment of AIDS-Related Non-Hodgkin's Lymphoma

Type of treatment:

d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Indinavir: antiretroviral, protease inhibitor
3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Chemotherapy, systemic: chemotherapy

Purpose:

To see if modified CHOP chemotherapy combined with triple antiretroviral therapy is effective in treating AIDS-related non-Hodgkin's lymphoma and in fighting HIV disease.

About the study:

All patients will receive low dose modified CHOP chemotherapy. CHOP chemotherapy is cyclophosphamide, doxorubicin, vincristine and prednisone. Chemotherapy is given by infusion into a vein every three weeks (one cycle). Patients will receive a minimum of four cycles or two cycles beyond complete response. No more than six cycles will be given. At the start of the second cycle, patients will take 3TC, d4T and indinavir. Viral load tests will be done at the beginning and middle of the first and second cycles of chemotherapy; then monthly for three months; then every three months. The study lasts one year

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Between 18 and 70 years old
- Biopsy-proven B-cell lymphoma

Not allowed:

- Patients with CNS lymphoma
- Current opportunistic infection, other than MAC, requiring antibiotic treatment
- Other cancers except cervical and basal cell
- Use of immunomodulators, such as interleukins or interferons, within two weeks of study entry
- Prior use of any protease inhibitors
- Women who are pregnant or breastfeeding

Location:

AIDS Oncology Practice at UCSF / Mt. Zion
Barbara Klencke, MD
(415) 567-5581

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Cheri Koppe
(916) 734-3604

UCLA CARE Center
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LAC-USC Medical Center - Norris Cancer Hospital
Joanne Shifflett, RN
(213) 226-4578

UCSF AIDS Program at SFGH/ICTG
Nelson Murcar, RN
(415) 476-9296, ext. 333

118. Non-Hodgkin's Lymphoma Treatment: IL-2

Title:

AMC003: Low-Dose Interleukin-2 in AIDS-Lymphoma: A CALGB Study

Type of treatment:

Interleukin-2: immune modulator

Purpose:

To see what effect interleukin-2 (IL-2) has on tumor response and survival and to see if it has any activity against HIV infection.

About the study:

Interleukin-2 is given by injection under the skin. Patients will be taught how to give themselves injections at home. Injections will be given every day for one year. Patients will need to come to the clinic every two weeks to pick up a supply of syringes already filled with IL-2. Study visits are at weeks 6, 10, 12, then every 12 weeks for one year.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 16 years old
- Diagnosis of non-Hodgkin's lymphoma that is in partial remission after completing standard therapy

Not allowed:

- Women who are pregnant or breastfeeding
- Current opportunistic infections
- Any other cancers other than basal cell of the skin
- CNS lymphoma
- Previous treatment with IL-2

Location:

AIDS Oncology Practice at UCSF / Mt. Zion
Barbara Klencke, MD
(415) 567-5581

LAC-USC Medical Center - Norris Cancer Hospital
Byron Espina
(213) 764-0371

UC Davis Cancer Center
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UCLA CARE Center
Christine MacNaughton
(310) 206-6414

UCSF AIDS Program at SFGH/ICTG
Sean Carnahan
(415) 476-9296 ext. 301

New

119. Non-Hodgkin's Lymphoma Treatment: Topotecan

Title:

104864/077: An Open, Non-Comparative, Phase II Study of Topotecan HCl Administered as a 30-Minute Infusion on Five Consecutive Days Every 21 Days to Patients with AIDS-Related Non-Hodgkin's Lymphoma

Type of treatment:

Topotecan: chemotherapy, systemic

Purpose:

To see how patients with non-Hodgkin's lymphoma respond to treatment with topotecan, how long the response lasts, how long it takes to respond to treatment, and how long it takes for lymphoma progression.

About the study:

All patients will receive topotecan. Topotecan is given by infusion into a vein through a 'PIC line'. A PIC line is a small tube (catheter) semi-permanently inserted into a vein in the arm. Infusions lasts about 30 minutes and are given five days in a row every 21 days. All patients go through at least two 21-day cycles, given four weeks apart. Study visits are once a week.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old

- Biopsy-proven diffuse large cell lymphoma; immunoblastic lymphoma; or small, non-cleaved lymphoma
- Must have received at least one but not more two prior treatments with chemotherapy
- Patients with under 200 T-cells must be receiving PCP prophylaxis

Not allowed:

- More than two prior treatments with chemotherapy
- Extensive radiation within the last two weeks
- Any change in antiretroviral therapy within the past two weeks
- Acute opportunistic infections
- Any infections requiring treatment with ganciclovir
- Any other cancers other than basal cell carcinoma or KS of the skin
- CNS lymphoma
- Women who are pregnant or breastfeeding

Location:

UCSF AIDS Program at SFGH/ICTG
Doug Raggett, RN
(415) 476-9296, ext. 312

New

120. Non-Hodgkin's Lymphoma Treatment: Diethylhomospermine

Title:

Diethylhomospermine (DEHSPM) in HIV-Associated Non-Hodgkin's Lymphoma: A Phase I/II Study

Type of treatment:

DEHSPM: chemotherapy

Purpose:

To see which dose of DEHSPM is best tolerated and to measure the response rate of non-Hodgkin's lymphoma.

About the study:

This is a dose-escalating study. That means that the first patients to enter the study will receive the lowest dose of DEHSPM. If no bad side effects are observed, the next group of patients will receive a higher dose, and so forth until the highest dose has been given that researchers plan to study or the highest dose is found that does not cause bad side effects. DEHSPM is given by injection under the skin every day for six days (one cycle) and the cycle is repeated every three weeks. Study visits are once a week and the study lasts until patients' disease gets worse.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Diagnosis of non-Hodgkin's lymphoma

Not allowed:

- Active opportunistic infections except herpes simplex or oral thrush (candida)

Location:

AIDS Oncology Practice at UCSF / Mt. Zion
Barbara Klencke, MD
(415) 567-5581

New

121. MAC Prevention: Azithromycin

Title:

ACTG 362: A Randomized, Placebo-Controlled Trial to Determine the Efficacy of Azithromycin Prophylaxis for the Prevention of Mycobacterium Avium Complex (MAC) and Other Infections in Subjects Who Have Achieved an Increase in CD4 Cells on Antiretroviral Therapy

Type of treatment:

Azithromycin: antibacterial

Purpose:

To compare the time to the development of MAC disease in patients taking azithromycin to those who are taking placebo in patients who have had an increase in their CD4 (T-cell) counts from below 50 cells/mm^3 to above 100 cells/mm^3.

About the study:

Patients are assigned by chance to receive azithromycin or placebo. Neither patients nor their doctors will know which they are receiving until the study ends. Both azithromycin and its placebo are pills and taken by mouth once a week. Patients who develop a drop in CD4 (T-cells) count below 50 on two separate occasions will be offered open-label (real) azithromycin. Study visits are every eight weeks. The study lasts at least 72 weeks.

Required:

- CD4 cell (T-cell) range: two counts of less than 50 on two separate occasions **OR** one count of less than 50 in the past and not known to be above 150 within three months prior to the count of less than 50 **AND** a treatment-induced increase of CD4 count to above 100 on two separate occasions
- HIV positive
- At least 13 years old
- Must be receiving antiretroviral therapy
- Patients receiving MAC prophylaxis at entry may be enrolled but must discontinue at study entry

Not allowed:

- Past or current use of IL-2
- Prior positive MAC culture from blood or other body site
- Known or suspected tuberculosis infection requiring therapy other than INH prophylaxis

- Concurrent treatment with azithromycin, clarithromycin, erythromycin, ethambutol, rifampin or rifabutin during the study

Location:

UCSD Treatment Center
Anne French, RN
(619) 543-8080 ext. 238

LAC-USC Medical Center
Luis Mendez, RN
(213) 343-8288

Harbor-UCLA Medical Center
Sandra Houston, LVN
(310) 222-5291

122. MAC Treatment: Clarithromycin, Rifabutin, Ethambutol

Title:

ACTG 223: A Phase II/III Prospective, Multicenter, Randomized, Controlled Trial Comparing the Safety and Efficacy of Three Clarithromycin-Containing Combination Drug Regimens for the Treatment of Disseminated Mycobacterium avium Complex (MAC) Disease in Persons with AIDS

Type of treatment:

Ethambutol: antimycobacterial
Clarithromycin: antibacterial
Rifabutin: antimycobacterial

Purpose:

To find out if clarithromycin is safe and helpful for treatment of MAC infection when used in combination with rifabutin and/or ethambutol.

About the study:

Everyone in the study takes clarithromycin. In addition, patients ar assigned by chance to receive rifabutin, ethambutol, or a combination of rifabutin and ethambutol. All patients will know which treatment thay are taking. The study lasts 48 weeks.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- MAC disease with symptoms and a positive blood culture
- Between 18 and 65 years old

Not allowed:

- Current treatment with Seldane or Hismanol
- Current treatment for active infection requiring fluconazole for more than 21 days
- Women who are pregnant or breastfeeding

Location:

UCSD Treatment Center
Anne French, RN
(619) 543-8080 ext. 238

UCSF AIDS Program at SFGH/ACTU
Carol Arri, RN
(415) 476-9296 ext. 351

LAC-USC Medical Center
Frances Canchola, RN
(213) 343-8281

New

123. Molluscum Contagiosum Treatment: Cidofovir Gel

Title:

GS-96-313: A Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of Cidofovir Gel for the Treatment of Molluscum Contagiosum in Patients with HIV Infection

Type of treatment:

Cidofovir Topical Gel: antiviral

Purpose:

To see if cidofovir gel is safe and effective in reducing molluscum contagiosum lesions and to measure the duration of regression.

About the study:

Patients are assigned by chance to receive cidofovir gel or placebo gel. Neither patients nor their doctors will know which they are receiving until the study ends. Patients will apply the gel to their lesions once a day. Study visits are once a week and the study lasts 16 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- At least 18 years old
- Diagnosis of molluscum contagiosum

Not allowed:

- No exclusions

Location:

UCSF AIDS Program at SFGH/ICTG
Anna Smith, RN
(415) 476-9296, ext. 313

124. Prurigo Nodularis: Thalidomide

Title:

Thalidomide for the Treatment of Refractory Prurigo Nodularis and Photodermatitis in Patients With HIV Infection

Type of treatment:

Thalidomide: cytokine inhibitor, antiwasting

Purpose:

To see if thalidomide is safe and effective as a treatment for itchy bumps on the skin associated with HIV infection. These bumps must be diagnosed as "Prurigo Nodularis" and not have responded to any other treatment.

About the study:

Patients are assigned by chance to receive one of two doses of thalidomide. All patients will take real thalidomide. A skin biopsy is required at the beginning and at the end of the study. A skin biopsy is the removal of a small piece of skin. The study lasts one year and study visits are every month. Blood will be drawn every three months.

Required:

- CD4 (T-cell) range: not specified
- HIV positive
- Prurigo nodularis (itchy skin bumps proven by biopsy) that have not gone away with steroid treatment
- 18 years of age or older

Not allowed:

- Pregnant or nursing women
- Moderate-severe peripheral neuropathy
- Currently taking ddC, d4T or systemic chemotherapy

Location:

SFGH Dermatology
Toby Maurer, MD
(415) 206-8680

125. TB Treatment: Rifapentine, Isoniazid, Rifampin

Title:

Efficacy and Safety of Once-Weekly Rifapentine and Isoniazid Compared to Twice-Weekly Rifampin and Isoniazid in the Continuation Phase of Therapy for Pulmonary Tuberculosis

Type of treatment:

Isoniazid: antimycobacterial
Rifampin: antimycobacterial
Rifapentine: antifungal

Purpose:

To compare two different treatment strategies for people with tuberculosis to learn which is easier to follow and more effective in preventing multi-drug resistant tuberculosis.

About the study:

Patients are assigned by chance to receive rifapentine and isoniazid pills once a week or rifampin and isoniazid pills twice a week for six months. Both treatments must be taken in the presence of a study employee, either at the clinic or at patients' homes, this is called "Directly Observed Therapy". The study requires monthly clinic visits for the first four months, then every three months for a year, and then two times in the last year for a total of 2 « years on study. Participants are compensated $20 a week for the first six months and then $10 per visit for the last two years.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive or negative
- Diagnosed with pulmonary TB
- Documented directly observed therapy with a 4-drug combination for 8 weeks
- Fully susceptible to INH and Rifampin
- At least 18 years old

Not allowed:

- Have received more than 70 days of treatment for tuberculosis at study entry
- Pregnant or breastfeeding women
- Other conditions requiring treatment with anti-TB drugs

Location:

San Francisco VA Medical Center
Bill Stanton, RN
(415) 221-4810, ext. 4798

LAC-USC Medical Center
Claudia Silva, RN
(213) 343-8268

126. TB Treatment: Rifampin, INH, Ethambutol, Pyrazinamide

Title:

ACTG 309: Pharmacokinetics of Antituberculosis Agents in HIV-Infected Persons with Tuberculosis

Type of treatment:

Pyrizinamide: antimycobacterial
Ethambutol: antimycobacterial
Isoniazid: antimycobacterial
Rifampin: antimycobacterial

Purpose:

To see how rifampin, INH, ethambutol and pyrazinamide are processed by the body in HIV-infected persons and to compare this to the way these drugs are processed in non-HIV-infected persons.

About the study:

Patients will take at least two and up to all four of the study drugs based on their doctor's decision. The study will cover the cost of the medications for eight weeks. Patients will know what medications they are taking. There are two study visits; one at week two and again at week six. These study visits are approximately 10 hours long and involve blood collection. Patients will be paid $25 for each 10 hour outpatient visit.

Required:

- CD4 cell (T-cell) range: unspecified
- Positive acid fast smear with TB cultures pending

Not allowed:

- Use of TB medications for more than one week prior to study entry

Location:

Harbor-UCLA Medical Center
Sally Kruger
(310) 222-3848

I27. Nutrition in HIV Infection: Peptamen, NuBasics, Vitamins

Title:

CPCRA 038: An Open-Label, Randomized, Three-Arm, Comparative Trial of a Caloric Supplement With Peptides and Medium-Chain Triglycerides Versus a Caloric Supplement With Whole Protein and Long-Chain Triglycerides Versus No Caloric Supplement for the Prevention of Weight Loss in Individuals With AIDS Who Take a Daily Multivitamin and Mineral Supplement

Type of treatment:

NuBasics: nutritional supplement
Peptamen: nutritional supplement

Purpose:

To compare two different supplements with no supplement for the prevention of weight loss in patients with AIDS who take a daily multivitamin and mineral supplement.

About the study:

Patients are assigned by chance to receive either Peptamen plus vitamins, NuBasics plus vitamins or vitamins alone. All patients will know which supplements they are taking Peptamen and NuBasics are liquids and patients drink two cans a day. Vitamins and minerals are in tablet form and patients take one tablet by moiuth per day. Patients will be evaluated for weight, body cell mass, activity level and dietary recall at baseline, month 2 and month 4. The study lasts four months and patients who complete the study will be offered a 30-day supply of the supplement of their choice (Peptamen or NuBasics) and a 30-day supply of the multivitamin supplement.

Required:

- CD4 cell (T-cell) range: less than 200
- Viral load range: not applicable
- HIV positive
- At least 13 years old
- Stable weight, defined as less than 5% weight loss in the past 3-6 months

Not allowed:

- Any acute opportunistic infection
- Any cancers other than stable KS that does not require chemotherapy
- Diabetes or phenylketonuria
- Any use of growth hormones, megace, marinol, thalidomide or steroids in the last 30 days
- Ongoing or recent use (more than 5 days during the previous 14 days) of caloric nutrition supplements used to promote weight gain
- Women who are pregnant or breastfeeding

Location:

Community Consortium
To be arranged through physician-see page 119
(415) 476-9554

I28. HIV Wasting Treatment: Nandrolone Decanoate

Title:

A Randomized, Double-Blind, Placebo-Controlled Study of Nandrolone Decanoate for HIV-Associated Wasting

Type of treatment:

Nandrolone Decanoate: anabolic steroid

Purpose:

To see if nandrolone decanoate is a safe and effective treatment for weight loss in people with HIV.

About the study:

Patients are assigned by chance to receive an injection of nandrolone decanoate or a placebo injection every week for 12 weeks. Neither patients nor their doctors will know which they are receiving until the study ends. After 12 weeks, all study patients will receive open-label nandrolone decanoate for an additional 12 weeks. Study visits will take place weekly and the study will last 24 weeks. Patients will be paid $500 for completing this study.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- Unintended loss of more than 10% of usual body weight
- Normal blood testosterone level
- At least 18 years old

Not allowed:

- Active opportunistic infection
- Use of other steroids, appetite-stimulating drugs or other drugs intended to treat weight loss, including growth hormone, megace, marinol, thalidomide, etc.
- Diarrhea, defined as more than five liquid stools per day
- Treatment for cancer other than KS
- Women who are pregnant or nursing

Location:

UCSF/SFGH Endocrinology
Heather Algren
(415) 206-3319

I29. HIV Wasting Treatment: Testosterone, Exercise

Title:

A Pilot, Randomized Study of Testosterone/Exercise for HIV Wasting

Type of treatment:

Exercise:
Testosterone: steroid

Purpose:

To see if testosterone alone or in combination with exercise is an effective treatment for HIV wasting.

About the study:

Patients are assigned by chance to receive injections of testosterone or placebo. Patients are also assigned by chance to participate in an exercise program at a specified gym or maintain their current activity level. Patients will know if they are assigned to exercise or maintain current activity but will not know if they are receiving testosterone or placebo until the study ends. The study requires two overnight stays at the hospital for body composition tests. Frequency of study visits will vary for each participant and the study lasts six months. Patients will be paid for their participation.

Required:

- CD4 cell (T-cell) range: not specified
- Men only
- HIV positive
- Blood testosterone level below normal
- Loss of 10% or more of usual body weight

Not allowed:

- Female patients

Location:

Harbor-UCLA Medical Center
Brenda
(310) 222-1859

130. HIV Wasting Treatment in Men: Oxandrolone

Title:

BTG/OXN-95-002: A Randomized, Double-Blind, Placebo-Controlled Study to Determine the Safety and Efficacy of Oxandrolone on Body Weight/Composition in HIV-Infected Male Patients

Type of treatment:

Oxandrolone: anabolic steroid

Purpose:

To see if oxandrolone is safe and effective in male patients experiencing unintentional weight loss. To see which dose of oxandrolone is most effective and safest.

About the study:

Patients are assigned by chance to receive one of three doses of oxandrolone or placebo. Neither patients nor their doctors will know which they are receiving until the study ends. Oxandrolone is a pill and taken by mouth. Study visits are every two weeks for the first month, then every four weeks. The study lasts 24 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- At least 18 years old
- 10-20% unintentional weight loss from a documented baseline weight
- Male patients only
- If patients are taking antiretroviral therapy, they must be on stable antiretroviral therapy for at least 6 weeks

Not allowed:

- Female patients
- 5% or more weight loss during the month prior to enrollment
- Any current AIDS-related opportunistic infections
- Treatment with any appetite-stimulating agents such as megace, marinol, prednisone or any other anabolic steroids, such as testosterone, nandrolone, growth hormone, within four weeks of study entry
- Current alcohol or substance abuse
- Any cancers other than KS which require systemic chemotherapy
- Patients requiring tube feeding
- Chronic diarrhea or fever
- Any eating disorder such as anorexia nervosa or bulimia, or any untreated thrush or oral herpes which interferes with eating

Location:

Marin County Specialty Clinic
Alison Clayton
(415) 499-6796

Kaiser San Francisco - HIV Research Unit
Barbara LeMaire, RN, MS
(415) 202-3486

Beer Medical Group
Heather Robertson
(213) 937-5151

Cedars-Sinai Medical Center
Jacqui Pitt, RN
(310) 855-3755

San Francisco VA Medical Center
Mae Pang, RN, MS
(415) 750-2005

131. HIV Wasting Treatment: Megace, Testosterone

Title:

ACTG 313: A Double-Blind, Randomized Comparison Phase II Trial of Megestrol Acetate and Testosterone Enanthate in Combination Versus Megestrol Acetate Plus Testosterone Enanthate Placebo in Human Immunodeficiency Virus (HIV)- Associated Wasting

Type of treatment:

Megace: appetite stimulant
Testosterone: steroid

Purpose:

To see if the predominant gain in fat rather than lean body mass that occurs when people take megestrol acetate (Megace) is improved by treatment with megace and testosterone.

About the study:

Patients are assigned by chance to receive megace plus testosterone or to receive megace plus placebo. Neither

patients nor their doctors will know if they are receiving testosterone until the end of the study. Megace is a liquid and is swallowed, while testosterone and its placebo are injections given into a muscle. After 12 weeks, all patients will take megace and real (no placebo) testosterone injections for an additional 12 weeks. Study visits (injections) are every two weeks and the study lasts 24 weeks. Patients will receive body composition analysis tests as part of the study. Some locations may pay patients for their participation.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Documented weight loss of >5% of pre-illness weight
- Blood testosterone levels must be normal for gender
- Patients on antiretroviral treatment must be on stable (no changes) treatment for at least 30 days prior to study entry

Not allowed:

- Any acute opportunistic infection within 30 days prior to study entry
- A weight gain of 3% or more during the preceeding four weeks
- Use of any interleukins, interferons, or anabolic treatments such as thalidomide, marinol, megace, growth hormone, steroids within 30 days of study entry
- Use of ketoconazole within 30 days of study entry
- Any history of allergy or sensitivity to megace or testosterone
- Diabetes mellitus
- Diarrhea defined as four or more liquid stools per day while using antidiarrheal medication
- Current use of systemic chemotherapy for any cancer other than KS
- Patients requiring total parenteral nutrition or tube feeding
- Severe nausea/vomiting
- Use of anticoagulant medications
- Patients with current or past cardiomyopathy or congestive heart failure
- Women who are pregnant or breastfeeding

Location:

UCSF AIDS Program at SFGH/ACTU
Carol Arri, RN
(415) 476-9296 ext. 351

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

LAC-USC Medical Center
Gil Clemente, RN
(213) 343-8284

132. HIV Wasting Treatment: Serostim

Title:

9037: A Phase IV, Randomized, Parallel Group, Double-Blind, Placebo-Controlled, Dose-Ranging Multicenter Study of Serostim, Mammalian Cell-Derived Recombinant Human Growth Hormone (r-hGH[m]), in the Treatment of HIV-Associated Catabolism/Wasting

Type of treatment:

Serostim: human growth hormone

Purpose:

To see if Serostim is effective in changing physical functioning capabilities in patients with AIDS wasting. To see which dose of Serostim works best to change lean body mass.

About the study:

Patients are assigned by chance to receive one of two doses of Serostim or placebo for the first twelve weeks of the study. After 12 weeks, those patients assigned to receive placebo will be assigned by chance to receive one of the two doses of Serostim. Neither patients nor their doctors will know which they are receiving until the study ends. Serostim is an injection given under the skin and will be given in the evening (preferably at bedtime). Patients and/or caregivers will be taught how to give injections. Body composition, physical function and quality of life wil be evaluated at weeks 12, 24 and 48. The study lasts about one year.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Diagnosis of AIDS wasting defined as: unintentional weight loss of at least 10% **OR** weight less than 90% of ideal body weight
- Must be receiving at least 100% of the estimated caloric requirement based on a formal nutritional analysis (to be done by the research staff)
- Must be taking an approved antiretroviral therapy for at least 8 weeks prior to study entry and no changes to this treatment during the first 12 weeks of the study

Not allowed:

- Current active opportunistic infections or malignancies, except KS of the skin
- Prior pancreatitis, carpal tunnel syndrome, glucose intolerance, angina, moderate to severe edema, coronary artery disease
- Women who are pregnant or breastfeeding
- Use of radiation therapy, chemotherapy, glucocorticords, or interferons
- Chronic diarrhea, defined as 6 or more liquid stools per day
- Unstable or untreated hypertension
- Active alcohol or substance abuse

Location:

Kaiser San Francisco - HIV Research Unit
Barbara LeMaire, RN, MS
(415) 202-3486

133. HIV Wasting Treatment: Thalidomide

Title:

W002: Compassionate Use of Thalidomde in Adults with HIV-Associated Wasting

Type of treatment:

Thalidomide: cytokine inhibitor, antiwasting

Purpose:

To allow patients who are HIV-infected and are wasting the opportunity to receive treatment with thalidomide.

About the study:

All patients will receive thalidomide for their wasting condition. Patients will be seen in the clinic every two weeks for the first month, then once a month for two months. After 12 weeks of treatment, patients will be evaluated and if further treatment is warranted, will continue taking thalidomide and be seen in the clinic once a month for a maximum of six months. After six months, patients may be re-enrolled if continued treatment is warranted based upon their doctor's evaluation.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Wasting, defined as involuntary weight loss of more than 10% from pre-illness body weight
- Women of childbearing potential must commit to either refraining from reproductive sexual intercourse **OR** to practice **TWO** methods of contraception; one barrier method and one hormonal method

Not allowed:

- Women who are pregnant or breastfeeding
- Severe peripheral neuropathy
- Previously discontinued thalidomide due to noncompliance, intolerance or because of a serious reaction to using thalidomide

Location:

Kaiser San Francisco - HIV Research Unit
Barbara LeMaire, RN, MS
(415) 202-3486

134. HIV Weight Loss in Women: Nandrolone Decanoate

Title:

ACTG 329: A Randomized, Double-Blind, Placebo-Controlled, Phase I/II Trial of Nandrolone Decanoate in Women With HIV-Associated Weight Loss

Type of treatment:

Nandrolone Decanoate: anabolic steroid

Purpose:

To see if nandrolone decanoate is a safe and effective treatment for women experiencing HIV-associated unintentional weight loss.

About the study:

Women will be assigned by chance to receive nandrolone decanoate or placebo. Nandrolone decanoate is given by injection into a muscle. Neither patients nor their doctors will know which they are receiving until the study ends. After 12 weeks, all patients will be eligible to receive open-label (real) nandrolone decanoate for an additional 12 weeks. Injections are given every two weeks. The study lasts 24 weeks. Patients in this study will receive body composition tests. Some locations may pay particcipants for their participation.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 13 years old
- Female
- Documented weight loss of >5% within the previous 12 months
- Patients taking antiretroviral therapy must have been on stable (no changes) therapy for at least 30 days prior to study entry

Not allowed:

- Males
- Active opportunistic infection or other major illness within 30 days of study entry
- Use of other anabolic therapy, such as steroids, growth hormone, thalidomide, megace, marinol, within 30 days of study entry
- Starting antiretroviral therapy within 30 days of study entry
- Women who are pregnant or breastfeeding
- Patients with a persistent palpable dominant breast mass at study entry that has not been evaluated
- Any history of cervical cancer. Patients with a high grade SIL or CIN2 or worse Pap smear are not eligible
- Diabetes mellitus
- Current or past congestive heart failure or cardiomyopathy
- Any condition requiring anticoagulation therapy while on study
- Persistent diarrhea, nausea, vomiting or impaired oral intake

Location:

UCSF AIDS Program at SFGH/ACTU
Carol Arri, RN
(415) 476-9296 ext. 351

LAC-USC Medical Center
Gil Clemente, RN
(213) 343-8284

135. HIV Wasting Treatment in Women: Oxandrolone

Title:

BTG/OXN-95-007: A Phase III Randomized, Double Blind Placebo Controlled Study to Determine the Safety and Efficacy of Oxandrolone on Body Weight and Composition in HIV-Infected Women

Type of treatment:

Oxandrolone: anabolic steroid

Purpose:

To see if oxandrolone is safe and to see its effect on body weight and body composition in HIV-infected women.

About the study:

Patients are assigned by chance to receive one of two doses of oxandrolone or placebo. Oxandrolone is in pill form and two pills are taken every day before breakfast. Neither patients nor their doctors will know which they are taking until the study ends. After 12 weeks, all patients will take open label (real) oxandrolone. Initially study visits will be once a week, then once a month. The study lasts 36 weeks. Some sites may pay patients for their participation.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Female patients only
- Documented involuntary weight loss of 10 - 20 % of average body weight
- If taking antiretroviral medications, must be on a stable dose for at least six weeks prior to enrollment

Not allowed:

- Male patients
- Weight loss of greater than 5% during the month prior to enrollment
- Current opportunistic infections
- Use of appetite stimulants or weight promoting agents within four weeks of study entry; such as Megace, Marinol, prednisone, testosterone, growth hormone
- Active alcohol or substance abuse
- Anorexia nervosa or bulimia
- Any cancers other than KS which require chemotherapy
- Ongoing chronic diarrhea defined as more than 3 liquid stools per day at least 4 days per week for more than 2 weeks
- Women who are pregnant or breastfeeding

Location:

AIDS Healthcare Foundation
Heather Churchill, RN
(213) 913-3953

Lyon-Martin Women's Health Services
Lynda Bell, RD
(415) 565-7672 ext. 313

136. HIV Weight Loss: Observational

Title:

Energy Balance and Wasting Syndrome

Type of treatment:

Observational: none

Purpose:

To study metabolism and collect data from patients with HIV weight loss.

About the study:

Patients joining this study should be experiencing some weight loss associated with HIV disease. There are two options for this study, inpatient or outpatient. The inpatient study requires four days in the hospital for metabolic rate testing and two outpatient visits. The inpatient study lasts three weeks and patients will be paid $400 for completing the study. The outpatient study requires three days of outpatient visits one week apart and those patients will be paid $250 for completing the study.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive

Not allowed:

- No exclusions

Location:

San Francisco VA Medical Center
Mae Pang, RN, MS
(415) 750-2005

137. HIV Wasting Syndrome: Observational

Title:

The Role of Malabsorption and Energy Deficit of the AIDS Wasting Syndrome

Type of treatment:

None: observational, natural history

Purpose:

To compare the treatment of malabsorption and energy expenditure in patients with weight loss and those without weight loss.

About the study:

Participants wil spend six to seven inpatient days in the General Clinical Research Center at San Francisco General Hospital. During their hospital stay, patients will have their diet monitored and their stools (feces) will be collected for analysis. Patients will also undergo blood tests and energy expenditure tests during their stay. All patients must have an endoscopy and sigmoidoscopy (internal examinations of the digestive tract) with biopsies (tissue samples taken) before enrolling in the study. There are five outpatient visits after the inpatient stay. The study lasts three weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- Patients with or without weight loss will be allowed to participate

Not allowed:

- Active opportunistic infections
- Treatable gastrointestinal infections

Location:

Division of Gastroenterology at SFGH
Johannes Koch, MD
(415) 206-4753

138. Nutrition in Women with HIV: Observational

Title:

Nutritional Assessment of Women Living with HIV

Type of treatment:

Observational: none

Purpose:

To learn about the effect of HIV disease on women's body composition (fat, muscle and bone). To learn how HIV disease affects the amount of energy used up by a woman's body when it is at rest. To learn how HIV disease affects women's eating habits. To compare these factors in women and men.

About the study:

This study consists mainly of body measurements and interviews. Every six months, patients come into the clinic for a two-hour study visit. Tests and measurements are done to determine body composition and patients are asked questions about the kind and amount of food they eat. Nutritional counseling is offered to patients who want it. The study lasts for an indefinite length of time. Patients are paid $25 at each visit.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- Female

Not allowed:

- No exclusions

Location:

UCSF/SFGH Endocrinology
Viva Tai, RD, MPH
(415) 206-4090

139. Human Herpes Virus 8 Project: Developmental

Title:

Pilot Project for the Development of a Branched-Chain DNA Assay for Human Herpes Virus 8

Type of treatment:

Observational: none

Purpose:

To see whether a laboratory test can be developed to detect and measure the amount of human herpes virus 8 in patients' blood samples.

About the study:

Patients with KS will be asked to provide one blood sample at one visit. Patients will be paid $25 for this one visit.

Required:

- CD4 cell (T-cell) range: not specified
- At least 13 years old
- Must have a diagnosis of Kaposi's sarcoma

Not allowed:

- No exclusions

Location:

Marin County Specialty Clinic
Alison Clayton
(415) 499-6796

140. HIV Transmission: Educational Intervention

Title:

HIV Prevention Intervention Study with an Embedded Observational Substudy

Type of treatment:

Observational: none

Purpose:

Toevaluate a behavioral intervention for heterosexual HIV-discordant couples and to identify biological factors that might be associated with prevention of HIV transmission in women who have been sexually exposed to HIV, but who remain uninfected.

About the study:

The main study is one year long and consists of a brief intensive intervention (one hour per week over four weeks) followed by two 30-minute booster sessions over a period of three months. Couples will be assigned by chance to receive intensive counseling for both partners or intensive counseling for the infected partner, with support and referrals for the negative partner. Participants will be seen at various locations throughout the Bay area. Every 6 months, participants will also be seen for a 2-hour study visit with interviews and lab tests for HIV, STD and pregnancy. The biological substudy consists of a brief visit at San Francisco General Hospital with a short survey, collection of blood, urine and semen samples and a brief pelvic examination for the women. The study lasts three years. Participants are paid for their participation.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive with an HIV-negative partner of the opposite sex **OR** HIV negative with an HIV-positive partner of the opposite sex

- Sexually active with that partner
- At least 18 years old

Not allowed:

- Unable to speak English or Spanish

Location:

California Partners Study
Kathy Bailey
(800) 262-2430

141. HIV Infection and the Central Nervous System: Observational

Title:

HIV Infection & Cognition: Observational

Type of treatment:

Observational: none

Purpose:

To learn more about the effects of HIV on the brain and thought processes.

About the study:

Participants are given a series of special examinations including a blood test, neurological examination, cognitive tests, brain wave recordings from metal disks placed on the scalp, and a magnetic resonance imaging (MRI) test. An MRI involves lying on a narrow bed in a recording tube in an MRI machine for about 2 hours. Participants are offered sedatives for this process, but must have an escort to accompany them home if they choose to be sedated. There are four study visits in a series and one series every 9 to 18 months. Results of the tests are made available to the participants and their physicians, and participants are paid for their time.

Required:

- CD4 cell (T-cell) range: 200 or below

-or-

- HIV negative

-or-

- HIV positive with cognitive impairment

Not allowed:

- Past or current toxoplasmosis or cryptococcal meningitis

Location:

Department of Psychiatry, UCSF / VA
Lynn Nielsen-Bohlman, PhD
(415) 476-7650

New

142. Pharmacokinetics: CPI-1189 (Lu 02-584)

Title:

Multiple Ascending Dose Pharmacokinetics of CPI-1189 (Lu 02-584) in Fasted, HIV-Infected Male Volunteers on Combined Retrovir, Epivir and Crixivan Therapy

Type of treatment:

CPI-1189:

Purpose:

To find out the safest and most-tolerated dose of CPI-1189 in HIV-infected but otherwise healthy men.

About the study:

This is a dose escalating study. This means that the first group of men to enter the study will receive the lowest dose of CPI-1189. If no bad side effects are seen, the next group of men will receive a higher dose, and so forth until the highest dose researchers plan to study has been given or the highest dose that does not cause bad side effects has been found. CPI-1189 is a pill and taken by mouth. Patients are required to have two hospital stays; one four days long and one two days. There are ten outpatient study visits. Patients will be paid $2,000 for completing the study.

Required:

- CD4 cell (T-cell) range: between 75 and 500
- Viral load range: not applicable
- HIV positive
- Between 18 and 50 years old
- Male patients only
- Must be taking AZT, 3TC and Crixivan for at least two months prior to study entry

Not Allowed:

- Any kidney, liver, cardiac or meta bolic diseases
- Female patients
- Men who have been sterilized
- Weight loss of more than 25% body weight
- Current bacterial, fungal or parasitic infections
- Current use of ketoconazole, itraconazole, chemotherapy or Tylenol
- Active alcohol or substance use

Location:

AIDS Research Center/Dept. of Veterans Affairs
Mark Mistal, RN, MSN
(415) 493-5000 ext. 64926

143. Pharmacokinetics: INH

Title:

Pharmacokinetics of Antituberculous Agents in HIV

Type of treatment:

Isoniazid: antimycobacterial

Purpose:

To learn how INH is absorbed and processed in the body. To compare the way this happens in men and women, and in people with AIDS and those who do not have HIV Infection.

About the study:

*This study is open to men and women with AIDS and men and women who do not have HIV infection. All patients take 300 mg. of INH every day for five days. Blood is drawn to measure the amount of INH in the blood. A small tube is inserted into the lungs to collect fluid and cells in order to measure the amount of INH that is absorbed into the lungs. There are several short study visits and one six-hour study visit. Patients are paid $350 for completing the study.

Required:

- CD4 cell (T-cell) range: not specified
- At least 18 years old
- AIDS or HIV-negative
- Negative PPD (skin test) for TB, negative chest x-ray for patients with HIV

Not allowed:

- Diarrhea, abdominal pain or cramping, nausea, vomiting
- HIV positive, but not meeting the CDC definition for AIDS
- Women who are pregnant or breastfeeding

Location:

UCSF Infectious Diseases Research
Elaine McKenna
(415) 476-2308

144. Pharmacokinetics: SCH 56592

Title:

C96-190-01: Pharmacokinetic Drug Interaction Study with Zidovudine/ Lamivudine and Protease Inhibitors in HIV-Infected Patients

Type of treatment:

SCH 56592: antifungal

Purpose:

To see if there are any drug interactions when SCH 56592 is given to HIV-infected patients who are taking a nucleoside analog drug and a protease inhibitor. To see if SCH 56592 is safe to take in combination with AZT, 3TC and protease inhibitors.

About the study:

Patients entering this study must be taking AZT, 3TC and either indinavir or ritonavir. They may not take any other drugs except those given as part of this study. All patients will be given SCH 56592 to take by mouth for 14 days. There will be two separate overnight hospital stays (4 days, 3 nights) and up to six outpatient visits lasting about an hour or less. The study lasts approximately 19 days. Patients will be paid $600 for completing the study

Required:

- CD4 cell (T-cell) range: at least 200
- Viral load range: not applicable
- HIV positive
- Between 18 and 45 years old
- Must be taking AZT, 3TC and either indinavir or ritonavir

Not allowed:

- Any other medications besides AZT, 3TC, indinavir or ritonavir without approval from the investigator
- No alcohol or caffeine during the study
- Any current acute opportunistic infections
- Prior hepatitis B or C
- Liver, kidney or heart disease
- Women who are pregnant or breastfeeding

Location:

UCSF Drug Research Unit at SFGH
Patty Lizak
(415) 476-5906

New

145. Pharmacokinetics: Indinavir, Rifabutin

Title:

ACTG 365: Steady-State Pharmacokinetic Interaction Study of Indinavir and Rifabutin

Type of treatment:

Rifabutin: antimycobacterial
Indinavir: antiretroviral, protease inhibitor

Purpose:

To see how the body processes indinavir and rifabutin when they are taken at the same time and at different times. To see if it is safe to take these two drugs together.

About the study:

Patients are assigned by chance to be in one of two groups. Patients in Group A will take study drugs for six weeks; patients in Group B for four weeks. Group A patients will take rifabutin by itself for the first two weeks, then indinavir and rifabutin for the next four weeks. Patients in Group B will take indinavir by itself for the first two weeks followed by indinavir plus rifabutin for an additional two weeks. Study visits are once a week and there are three 24-hour study days (two for Group B) where patients will have multiple blood draws. The study lasts seven weeks for Group A and five weeks for Group B.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Between 18 and 60 years old
- Patients must take at least one antiretroviral nucleoside analog, such as AZT, ddC, 3TC or d4T. ddI is not allowed during the study

Not allowed:

- Active opportunistic infections

- Women who are pregnant or breastfeeding
- Use of ddI during the study
- Prior use of indinavir for **Group A**; prior use of indinavir is allowed for **Group B**
- Use of rifampin, triazolam, midazolam, astemizole, nevirapine, phenobarbital or any investigational drug within 14 days of study entry
- Patients requiring maintenance therapy for active opportunistic infections, except acyclovir for herpes simplex
- Active alcohol or substance abuse
- Past episode of kidney stones

Location:

LAC-USC Medical Center
Connie Olson, RN
(213) 343-8279

I46. Mother-Newborn Transmission Prevention: Nevirapine

Title:

Pediatric ACTG 316: A Phase III Randomized, Blinded Study of Nevirapine versus Nevirapine Placebo for the Prevention of Maternal-Fetal Transmission in Pregnant HIV-Infected Women Who Present During the Third Trimester of Pregnancy

Type of treatment:

Nevirapine: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI

Purpose:

To find out if taking nevirapine during labor prevents infants of HIV-infected mothers from becoming infected with HIV.

About the study:

HIV-infected pregnant women will be assigned by chance to receive nevirapine or placebo during labor. Nevirapine and its placebo are taken by mouth. Women wil take a single dose of nevirapine (or its placebo) during active labor. The newborn infant will also receive a single dose of nevirapine (or placebo) between 48 and 72 hours after it is born. Mothers will be encouraged to also take AZT during their pregnancy (in accordance with US Public Health Service guidelines). Mothers and their infants will have follow-up study visits at one month, 3 months and 6 months after the infant is born.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive pregnant women
- At least eight months pregnant

Not allowed:

- Prior use of nevirapine, delavirdine or any other non-nucleoside reverse transcriptase inhibitor
- Participation in any other perinatal treatment study

Location:

LAC-USC Medical Center - Maternal Child Program
Melissa Scanlon, RN
(213) 226-5095

Bay Area Perinatal AIDS Center (BAPAC)
Maureen Shannon, FNP / CNM
(415) 206-8919

UCSD Treatment Center - Pediatrics
Myrene Preston
(619) 543-8080 ext. 204

I47. HIV Infection in Women: VIRACEPT, Invirase, 3TC, d4T

Title:

AG1343-534: Phase II, Randomized Study of the Safety and Efficacy of VIRACEPT (BID) and Saquinavir (BID) Administered in Combination with Stavudine (d4T) and Lamivudine (3TC) Versus VIRACEPT (TID) and Saquinavir (TID) Administered in Combination with Stavudine (d4T) and Lamivudine (3TC) in HIV-Positive Women

Type of treatment:

Nelfinavir: antiretroviral, protease inhibitor
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Invirase: antiretroviral, protease inhibitor
3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see how VIRACEPT and saquinavir (Invirase), in combination with d4T and 3TC, are processed by womens' bodies. To see if these combinations are safe and effective for HIV-positive women to take. To observe gynecological events associated with HIV disease

About the study:

All women will receive 3TC and d4T and will be assigned by chance to receive one of two doses of VIRACEPT and saquinavir. Patients will know which doses of VIRACEPT and saquinavir they are taking. All medications are pills and taken by mouth. Study visits are every two weeks for the first month, then once a month. A cervical lavage and pap smear will be performed during this study. The study lasts one year.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: at least 10,000 copies/mL
- HIV positive
- Female patients only
- At least 13 years old
- Must be antiretroviral naive or have less than one month cumulative exposure to d4T and/or 3TC

Not allowed:

- Male patients
- Prior use of any antiretrovirals. Less than one month cumulative use of d4T and/or 3TC is allowed
- Prior use of any protease inhibitors
- Use of any immune modulators or vaccines within one month of study entry
- Any cancers requiring chemotherapy or radiation therapy or any use of such treatments within one month of study entry
- Acute pancreatitis or hepatitis
- Past episode(s) of bilateral peripheral neuropathy
- Women who are pregnant or breastfeeding
- Active alcohol or substance abuse

Location:

LAC-USC Medical Center
Luis Mendez, RN
(213) 343-8288

148. HIV Infection in Pregnant Women: ddI

Title:

Pediatric ACTG 249: A Phase I Trial to Evaluate Didanosine (ddI) in HIV-1 Infected Pregnant Women

Type of treatment:

ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see if ddI is safe and effective for treating women in their third trimester of pregnancy. To see how ddI is absorbed and processed by the bodies of pregnant women. To determine the effects of ddI on the newborn infant of mothers treated with ddI during the third trimester.

About the study:

All patients will receive a one-hour infusion (injection into a vein) of ddI. Patients will then take ddI by mouth twice a day until the onset of labor. During labor, patients will receive another infusion of ddI until delivery. Study visits are every two weeks and patients will be in this study from 3 to 5 months.

Required:

- CD4 cell (T-cell) range: between 50 and 350
- HIV positive
- At least 13 years old
- Fetal age of at least 26 weeks but not more than 36 weeks, based on last menstrual history
- Not able to take AZT due to side effects or failure of AZT

Not allowed:

- Past stillbirth, neonatal death or a previous infant with malformations
- Current obstetrical complications
- Expected multiple birth
- Past maternal medical complications such as, malabsorption, pancreatitis, neurological complications including peripheral neuropathy, CMV requiring ganciclovir or foscarnet
- Current use of steroids, INH (isoniazid), IV pentamidine or current regular alcohol use
- Current antiretroviral therapy with anything other than ddI

Location:

UCLA Medical Center - Pediatrics
Leslie Spring
(310) 206-6369

New

149. HIV Infection in Pregnant Women: Indinavir, AZT, 3TC

Title:

Pediatric ACTG 358: A Phase I Trial of the Safety,Tolerance and Pharmacokinetics of Oral Indinavir Co-Administered with Lamivudine (3TC) and Zidovudine (ZDV) in HIV-1 Infected Pregnant Women During Gestation and Post Partum, and in Their Infants Post Maternal Dosing

Type of treatment:

AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Indinavir: antiretroviral, protease inhibitor
3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see if indinavir, when combined with AZT and 3TC, is safe and well-tolerated in pregnant women and to see how these drugs are processed by womens' bodies. To determine what dose to give to the newborn infant.

About the study:

Participants will take indinavir (Crixivan), AZT and 3TC by mouth from the start of the study until 12 weeks after their babies are delivered. Women will come to the clinic every two weeks until week 36 of their pregnancy, then once a week until the start of labor. Mothers will have ultrasound performed between 18 and 20 weeks of pregnancy and every four weeks after week 26 of pregnancy. For three study visits, patients will come to the clinic before taking their morning dose of indinavir. One of these study visits will be about eight hours long. Mothers in active labor must STOP taking indinavir and will receive their

AZT by infusion into a vein. There are study visits at 6 and 12 weeks after giving birth. Newborn babies will take AZT and 3TC when they are taking liquids and will continue for six weeks. Babies will have study visits at 8 days, 3 weeks, 6 weeks, 3 months, and 6 months after birth.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 13 years old
- Pregnant with a gestational age of at least 14 weeks to 28 weeks, based upon menstrual history and confirmed by ultrasound or sonograph
- Patients must be willing and able to drink six 8-ounce glasses of water a day

Not allowed:

- Prior treatment with any protease inhibitors
- Treatment with 3TC prior to pregnancy **OR** more than three weeks treatment during this pregancy
- Treatment with any NNRTIs, such as delavirdine or nevirapine, within three weeks prior to study entry
- Current alcohol or substance abuse
- Active opportunistic infections
- Chronic malabsorption or diarrhea
- Chronic liver or kidney disease including kidney stones

Location:

UCSD Treatment Center - Pediatrics
Myrene Preston
(619) 543-8080 ext. 204

New

150. HIV Infection in Pregnant Women and Infants: Nelfinavir, AZT, 3TC

Title:

ACTG 353: A Phase I Trial of the Safety, Tolerance and Pharmacokinetics of Oral Nelfinavir (VIRACEPT) Co-Administered with Zidovudine (ZDV) and Lamivudine (3TC) in HIV-Infected Pregnant Women and Their Infants

Type of treatment:

Nelfinavir: antiretroviral, protease inhibitor
3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see if nelfinavir is safe and effective in treating HIV infection when given in combination with AZT and 3TC to pregnant women. To see how nelfinavir is processed in pregnant womens' bodies and to see how it is processed in the newborn infant.

About the study:

Participants will receive AZT, 3TC and nelfnavir from the start of the study until 12 weeks after delivering their babies. Women will come to the clinic every two weeks until week 36 of their pregnancy, then once a week until the start of labor. Mothers will have ultrasound performed between 18 and 20 weeks of pregnancy and every four weeks after week 26 of pregnancy. After taking study drugs for about two weeks, mothers will have a nine-hour study visit for multiple blood draws. Mother in active labor will receive their AZT by infusion into a vein. Newborn babies will being taking nelfinavir, AZT and 3TC when they are taking liquids and continue taking study medications for six weeks. Babies will have study visits at 8 days, 3 weeks, 6 weeks, 3 months and 6 months of life.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 13 years old
- Pregnant with a gestational age of at least 14 weeks but no more than 34 weeks, based upon menstrual history and confirmed by ultrasound or sonograph

Not allowed:

- Past use of any protease inhibitors
- Treatment with 3TC prior to pregnancy **OR** more than three weeks treatment during this pregnancy
- Use of NNRTIs, such as delavirdine or nevirapine, within two weeks of study entry
- Active alcohol or substance abuse
- Active opportunistic infections
- Chronic malabsorption or diarrhea

Location:

LAC-USC Medical Center - Maternal Child Program
Melissa Scanlon, RN
(213) 226-5095

151. HIV Infection in Women in Labor: AZT

Title:

Pediatric ACTG 324: A Phase I Trial of the Pharmacokinetics and Tolerance of Oral Zidovudine Administered to HIV-1 Infected Pregnant Women During Labor and Delivery

Type of treatment:

AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see how AZT is processed by the body when taken by mouth in HIV-positive women during labor and delivery

About the study:

This study invloves two groups of patients. At the onset of labor, the first group of patients will take three doses of AZT, three hours apart. Blood samples will be taken after each dose. After the last dose of AZT is taken by mouth, patients will take AZT by infusion into a vein until delivery of the baby. If no problems occur with the first group of patients, the second group will follow the same plan, except they will continue taking AZT by mouth after the third dose, rather than taking AZT by infusion into a vein. Patients will return to the clinic one week after delivery, and again four to eight weeks and six to eight months after delivery. Blood samples will be taken at each visit.

Required:

- CD4 cell (T-cell) range: not applicable
- Mothers must be HIV positive
- Mothers must be at least 34 weeks pregnant, confirmed by pelvic exam or ultrasound
- Prior treatment with AZT for at least 28 days during this current pregnancy

Not allowed:

- Use of any antiretroviral other than AZT
- Any active opportunistic or other serious infection at the time of study entry
- Intrauterine growth retardation
- Elective cesarean section
- Participation in any other perinatal treatment trial during this pregnancy

Location:

UCLA Medical Center - Pediatrics
Leslie Spring
(310) 206-6369

Bay Area Perinatal AIDS Center (BAPAC)
Maureen Shannon, FNP / CNM
(415) 206-8919

UCSD Treatment Center - Pediatrics
Myrene Preston
(619) 543-8080 ext. 204

152. HIV Exposure in Premature Infants: AZT

Title:

Pediatric ACTG 331: The Safety, Tolerance and Pharmacokinetics of Zidovudine in Premature Infants Exposed to HIV

Type of treatment:

AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To learn how AZT is absorbed and processed in premature infants exposed to HIV. To learn about the safety of using AZT in premature infants.

About the study:

Infants who are born prematurely and who will receive AZT as part of their clinical care will be enrolled in this study. The study requires nine blood samples collected over 30 days, and some additional clinical laboratory tests collected over 12 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: not applicable
- Premature infant (34 weeks gestation or less)
- Less than 5 days old
- Infant should receive AZT, in the opinion of the primary care provider

Not allowed:

- Life-threatening illnesses
- Infant not expected to survive beyond six weeks

Location:

UCLA Medical Center - Pediatrics
Leslie Spring
(310) 206-6369

LAC-USC Medical Center - Maternal Child Program
Melissa Scanlon, RN
(213) 226-5095

UCSD Treatment Center - Pediatrics
Myrene Preston
(619) 543-8080 ext. 204

153. HIV Infection in Newborns: 1592U89, AZT

Title:

Pediatric ACTG 321: Phase I Study of Safety, Tolerance, and Pharmacokinetics of 1592U89 with Standard Zidovudine (ZDV) Therapy in Neonates Born to HIV-1 Infected Mothers

Type of treatment:

AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
1592U89: antiretroviral

Purpose:

To find out the amount of 1592U89 there is in the blood of newborn babies who receive a single dose of 1592U89 in addition to AZT. To compare the safety of different doses of 1592U89.

About the study:

This is a dose escalating study. This means that the first group of patients entering the study will receive the lowest dose of 1592U89. If no bad side effects are seen, the next group of patients will receive a higher dose of

1592U89. This study consists of two parts: Part 1 and Part 2. Part 1 has two groups: A and B. Group A is for infants 0 - 72 hours of age; Group B is for infants 21-28 days of age. Both groups will receive a single dose of 1592U89 and AZT on the first day. They will continue to take AZT four times a day for six weeks. 1592U89 and AZT are taken by mouth. Five study visits are required for Part 1. Part 2 is a study of multiple doses of 1598U89 in infants 0-72 hours of age. All patients will take 1592U89 and AZT every day for six weeks. Six study visits are required. The study lasts eight weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- Infants born to HIV-infected mothers
- **Part 1A**: Infants between birth and 72 hours old
- **Part 1B**: Infants between 21 and 28 days old

Not allowed:

- Infants with major congenital abnormalities
- Exposure (through the mother) to any protease inhibitors or NNRTIs
- Any serious infections requiring treatment during the study

Location:

LAC-USC Medical Center - Maternal Child Program
Melissa Scanlon, RN
(213) 226-5095

I54. HIV Infection in Infants and Children: AZT, 3TC, Nevirapine, 1592U89

Title:

Pediatric ACTG 356: ZDV/3TC/Nevirapine and ZDV/3TC/Nevirapine/1592U89 Combination Therapy in HIV-1 Infected Infants and Children

Type of treatment:

AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Nevirapine: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI
1592U89: antiretroviral

Purpose:

To compare the safety and effectiveness of a triple-drug therapy to a quadruple-drug therapy in HIV-infected infants and children and to see if they can reduce the HIV RNA viral load.

About the study:

There are two parts to this study. Part A will enroll patients to a triple drug combination using AZT, 3TC and nevirapine. All patients will receive active medication; there are no placebos in this study. If, after 12 weeks, 75% of the patients in Part A achieve a viral load reduction to <1,000 copies/mL, then Part A will continue. If 75% of patients do not achieved a viral load reduction to <1,000 copies/mL after 12 weeks, Part A will stop and Part B will begin to enroll. Patients in Part B will receive a quadruple combination therapy using AZT, 3TC, nevirapine and 1592U89. Study visits are once a month and the study lasts 104 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Between 15 days through two years old

Not allowed:

- More than six weeks of prior antiretroviral therapy, or any past infant use of nevirapine, or any mother who used nevirapine for more than two weeks
- Use of any other antiretrovirals, other investigational drugs, immunomodulators or HIV vaccines throughout the study
- Past clinical pancreatitis **PART B ONLY**
- Infant use of more than one single dose of 1592U89

Location:

UCSF Pediatric Immunology Program
Deborah Trevithick, RN, MS
(415) 476-6480

UCSD Treatment Center - Pediatrics
Myrene Preston
(619) 543-8080 ext. 204

Children's Hospital, Oakland
Teresa Courville, RN, MN
(510) 428-3885, ext. 2827

New

I55. HIV Infection in Infants: ALVAC HIV Vaccine

Title:

Pediatric ACTG 326: A Phase I/II Study to Evaluate the Safety and Immunogenicity of ALVAC HIV Vaccine Alone or with a Subunit Vaccine in Children Born to HIV-Infected Mothers

Type of treatment:

ALVAC Vaccine: vaccine

Purpose:

To see if canarypox HIV ALVAC vaccine is safe and effective in producing an immune response, when used alone or in combination with another vaccine, in infants born to HIV-infected mothers. To see how these vaccines affect the baby's immune system.

About the study:

HIV-infected mothers will be enrolled in this study when they are 37 weeks pregnant or as soon thereafter as possible. Newborn babies will be assigned by chance to receive either the ALVAC vaccine or placebo. Neither parents nor the baby's doctor will know

which they are receiving until the study ends. The vaccine and its placebo are given by injection into the baby's thigh within 72 hours of birth and at 1, 2 and 3 months of age. The first two groups of babies will receive only the ALVAC vaccine or placebo. At a later date, when another vaccine product becomes available, another group of babies will be assigned by chance to receive either the ALVAC vaccine plus the new vaccine or placebo. Babies will have to stay in the clinic for one hour after each vaccine shot and return to the clinic 48 hours after each shot to be checked for problems. Study visits are every two weeks for the first 14 weeks of life, then every six months until the baby is two years old. There are a total of 12 study visits and the study lasts two years.

Required:

Mothers
- HIV positive
- At least 37 weeks pregnant

Babies
- Less than 72 hours old
- May be receiving antiretroviral therapy

Not allowed:

Mothers
- Use of any investigational drug during pregnancy
- Use of passive or active immunotherapy during pregnancy
- Positive Hepatitis B antigen at study entry

Babies
- Receipt of any investigational therapy
- Receipt of passive or active HIV-specific immunotherapy
- Documented or suspected serious bacterial infection or metabolic illness
- Infants being breastfeed

Location:

UCSD Treatment Center - Pediatrics
Myrene Preston
(619) 543-8080 ext. 204

156. HIV Infection in Children: bis-POM PMEA

Title:

Pediatric ACTG 310: A Phase IA Single Dose Pharmacokinetics and Safety Study of the Oral Antiviral Compound bis-POM PMEA (Adefovir Dipivoxil) in Children with HIV-1 Infection

Type of treatment:

Adefovir dipivoxil: antiretroviral, reverse transcriptase inhibitor, nucleotide analog

Purpose:

To see if bis-POM PMEA is safe for children to take and to see which dose is best tolerated. To see how bis-POM PMEA is processed by childrens' bodies.

About the study:

Children entering this study will be given the lowest of two doses of bis-POM PMEA. bis-POM PMEA is a pill and taken by mouth. Patients will only take the medication once and will only be studied once. After safety data has been gathered, the next patients will take the higher dose of bis-POM PMEA. The study lasts one day and will last all day long so timed blood and other tests can be taken.

Required:
- HIV positive
- Less than one year old

Not allowed:
- Patients taking any of the following must discontinue them beginning 72 hours before and continuing 72 hours after the study dose: any other antiretroviral agents; other investigational agents; immunomodulators; HIV vaccines, Bactrim/Septra or Dapsone, acyclovir, ganciclovir, foscarnet, pentamidine Amphotericin B
- Females who are pregnant

Location:

UCSF Pediatric Immunology Program
Deborah Trevithick, RN, MS
(415) 476-6480

157. HIV Infection in Children: rIL-2

Title:

Pediatric ACTG 299: Phase I/II Trial of Recombinant Interleukin-2 in Symptomatic Human Immunodeficiency Virus-Infected Children

Type of treatment:

Interleukin-2: immune modulator

Purpose:

To see if interleukin-2 is safe and effective for treating children who are HIV-infected. To find the highest dose of interleukin-2 that is safest for children to take.

About the study:

This is a dose escalating study. This means that the first patients to enter the study wil receive the lowest dose of interleukin-2. If this dose is tolerated with no bad side effects, the next group of patients will receive the next highest dose level and so forth until the highest dose that is tolerated with no bad side effects is found (Part A). Once the maximum tolerated dose has been determined, additional patients will be enrolled to receive that dose (Part B). Interleukin-2 is given as an infusion into a vein. Children will receive a continuous infusion for five days in a row every eight weeks. This is called a cycle and children will complete three cycles. Those children who participated in Part A and did not receive the maximum tolerated dose of interleukin-2 will be eligible to participate in Part B to receive that dose. Parts A and B both last 44 weeks.

Required:

- CD4 cell (T-cell) range:
  age 3-5 years: 500 - 1000
  age 6-12 years: 200 - 500
- Viral load range: not applicable
- HIV positive
- Between 3 and 12 years old. Patients are eligible if they enter the study prior to their 13th birthday
- Patients must be receiving the best available antiretroviral therapy for at least one month and not more than 12 months prior to study entry
- Children must have symptomatic HIV infection

Not allowed:

- Any active opportunistic infection
- Any steroids or other immunosupressive therapy
- Current polyclonal or monoclonal antibody therapy
- Current use of IVIG
- Females who are pregnant

Location:

UCSF Pediatric Immunology Program
Deborah Trevithick, RN, MS
(415) 476-6480

I58. HIV Infection in Children: I592U89, AZT, 3TC

Title:

CNAA3006: A Double-Blind, Randomized Multicenter Trial to Evaluate the Safety and Efficacy of the Combination of 1592U89 + Zidovudine (ZDV) + Lamivudine (3TC) Versus the Combination of Zidovudine (ZDV) + Lamivudine (3TC) in HIV-1 Therapy-Experienced Pediatric Patients

Type of treatment:

1592U89: antiretroviral
3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see which combination is safest and best at reducing the amount of HIV virus in the blood.

About the study:

All patients will take AZT and 3TC. Patients are assigned by chance to receive 1592U89 or placebo. Neither patients nor their doctors will know if they are taking 1592U89 or not until the study ends. All medications are pills and taken by mouth. Study visits are once a month and the study lasts about a year.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: at least 10,000 copies/mL
- HIV positive
- Between three months and 13 years old

Not allowed:

- Past or current opportunistic infections

Location:

LAC-USC Medical Center - Maternal Child Program
Melissa Scanlon, RN
(213) 226-5095

New

I59. HIV Infection in Children: CD4-IgG2

Title:

Pediatric ACTG 351: Phase I/II Trial of CD4-IgG2 in HIV-1 Infected Children

Type of treatment:

CD4-IgG2: viral blocker

Purpose:

To see if CD4-IgG2 is safe and to see what effect it has against the HIV virus in children. To see how CD4-IgG2 is processed by childrens' bodies.

About the study:

This study has two parts. Part 1 is a dose-escalating study. This means that the first group of children to enroll will receive the lowest dose of CD4-IgG2. If no bad side effects are seen, the next group of children will receive a higher dose and so forth until the fourth group of children get the higest dose of CD4-IgG2. CD4-IgG2 is given once by infusion into a vein. The infusion lasts about one hour and children will have to stay overnight in the hospital on the day they receive the infusion. There will be several blood draws on the day of the infusion. Study visits are on days 1, 3, 7, 14 and 28 following the single infusion. There will be blood draws on these days. There will also be visits at 2, 3 and 4 months after the single infusion. Part 1 lasts four months. Children who enroll in Part 2 will receive infusions of CD4-IgG2 once a week for four weeks. The dose given will be established from Part 1. Children will have to stay overnight in the hospital each day the infusion is given. After the last infusion (week 3), blood will be drawn at 1, 2, 6, 24 hours, 7 days, and 14 days to see how much CD4-IgG2 is in the blood. Study visits will be at weeks 7, 11, 15 and 19. Part 2 lasts five months.

Required:

- CD4 cell (T-cell) range:
  age 2-5 years: less than 500
  age 6-12 years: less than 200
- Viral load range **(Part 2 ONLY)**: at least 10,000 copies/mL
- HIV positive
- Between 2 and 12 years old
- Stable (no changes) antiretroviral therapy for at least three months prior to study entry

Not allowed:

- Active opportunistic infections
- Females who are pregnant
- Use of steroids or other immunosuppressive therapy
- Children receiving IVIG

- Children currently participating in a vaccine trial
- Any routine vaccination within 30 days of study entry

Location:

UCSF Pediatric Immunology Program
Deborah Trevithick, RN, MS
(415) 476-6480

160. Infant Immune Response: Pneumococcal Conjugate Vaccine

Title:

Pediatric ACTG 292: A Double Blind, Placebo-Controlled Trial of the Safety and Immunogenicity of a Seven Valent Pneumococcal Conjugate Vaccine in Presumed HIV-Infected Infants

Type of treatment:

Pneumococcal vaccine: vaccine

Purpose:

To learn if infants who receive a pneumococcal conjugate vaccine have more of a reaction at the site of injection and in the body than those who receive placebo. To learn if infants who receive a pneumococcal conjugate vaccine develop more pneumococcal antibody than those receiving placebo.

About the study:

Patients are assigned by chance to receive either pneumococcal conjugate vaccine or placebo. Neither parents nor their doctors will know which they are receiving until the study ends. The study lasts until the infant is 2 years old. There are 10 study visits. Injections will be given at the beginning of the study, 2 months after the study begins, 4 months after the study begins, and at 15 months of age. All infants will receive the licensed pneumococcal polyvalent vaccine at 24 months of age.

Required:

- CD4 cell (T-cell) range: not specified
- Between 56 and 180 days old
- Presumed HIV infection

Not allowed:

- Use of blood products (such as IVIG, VZIG, HbIG, transfusions) within 56 days before joining the study
- Vaccination with pneumococcal vaccine
- Congenital immunoglobulin deficiency, SS or SC hemoglobinopathy, or asplenia
- Use of any immunosuppressant drug (including prednisone) for more than 6 weeks

Location:

UCSF Pediatric Immunology Program
Deborah Trevithick, RN, MS
(415) 476-6480

LAC-USC Medical Center - Maternal Child Program
Melissa Scanlon, RN
(213) 226-5095

UCSD Treatment Center - Pediatrics
Myrene Preston
(619) 543-8080 ext. 204

Children's Hospital, Oakland
Teresa Courville, RN, MN
(510) 428-3885, ext. 2827

161. Bacterial Infection Prevention in Children & Adolescents: Antibiotics

Title:

Pediatric ACTG 254: A Randomized, Phase II/III, Double Blind, Placebo Controlled, Two-armed Study of Micronized-Atovaquone and Azithromycin as Compared to Trimethoprim-Sulfamethoxazole in the Prevention of Serious Bacterial Infections When Used in Children Aged 3 Months to 18 Years with HIV Infection.

Type of treatment:

Trimethoprim-Sulfamethoxazole: antibacterial
Atovaquone: antibacterial
Azithromycin: antibacterial

Purpose:

To find out if taking the drugs atovaquone and azithromycin together is as good or better than taking Septra alone in preventing serious bacterial infections.

About the study:

Patients are assigned by chance to receive atovaquone and azithromycin and placebo or Septra and placebo. All drugs are taken by mouth. Neither the patients nor their doctors know which drugs they are taking until the study ends. The study lasts two years.

Required:

- CD4 cell (T-cell) range: not specified
- Between 3 months and 18 years old
- HIV positive
- At risk for developing PCP

Not allowed:

- Active PCP
- Past use of atovaquone or azithromycin
- Being treated for MAC, toxoplasmosis, tuberculosis, cryptosporidiosis or microsporidiosis
- Females who are pregnant

Location:

UCSF Pediatric Immunology Program
Deborah Trevithick, RN, MS
(415) 476-6480

UCLA Medical Center - Pediatrics
Leslie Spring
(310) 206-6369

LAC-USC Medical Center - Maternal Child Program
Melissa Scanlon, RN
(213) 226-5095

UCSD Treatment Center - Pediatrics
Myrene Preston
(619) 543-8080 ext. 204

Children's Hospital, Oakland
Teresa Courville, RN, MN
(510) 428-3885, ext. 2827

162. Congenital CMV Infection: Ganciclovir

Title:

Evaluation of Ganciclovir (DHPG) for the Treatment of Symptomatic Congenital Cytomegalovirus Infections

Type of treatment:

Ganciclovir, IV: antiviral

Purpose:

There is currently no licensed drug to treat congenital CMV infection. This study will see if treatment with ganciclovir (DHPG) is better or worse than no drug treatment in infants. The study will look at the risks versus the benefits of using either ganciclovir or not treating with the medication.

About the study:

Babies with symptomatic congenital CMV infection will be assigned by chance to receive ganciclovir or to receive no medication. Ganciclovir is given by infusion (into a vein) for one hour twice a day. Infusions will be given for a period of six weeks. After six weeks of treatment, babies will be examined at two and four weeks for eye and neurologic symptoms. Long-term studies will be performed at six month intervals (twice) then annually. Babies assigned to no treatment will be monitored and evaluated the same as babies receiving treatment.

Required:

- Between two weeks and one month old
- Confirmed CMV in cultures of throat, urine and white blood cells
- Evidence of CNS involvement such as microcephaly, abnormal CSF for age, chorioretinitis, hearing defects

Not allowed:

- Gestational age less than 32 weeks
- Mild symptomatic or asymptomatic congenital CMV infections
- Weight leas than 1,200 grams at birth
- Currently using other antivirals or immune globulin

Location:

LAC-USC Medical Center - Maternal Child Program
Melissa Scanlon, RN
(213) 226-5095

163. Growth and Nutritional Status in Infants: Infant Formula

Title:

Pediatric ACTG 247: A Randomized, Double-Blind, Controlled Study of an Increased Caloric Density Infant Formula and its Effect on Growth and Nutritional Status in HIV-Infected Infants

Type of Treatment:

Infant Formula

Purpose:

To compare a higher calorie formula to a standard calorie formula and to see its effect on improved growth in HIV-infected infants.

About the study:

Newborns of HIV-infected mothers are assigned by chance to receive a higher calorie formula or standard calorie formula. After eight weeks, infants with negative HIV-specific tests (presumed HIV negative) will be assigned by chance to discontinue the study or to continue the study using the standard calorie formula. Those infants who are HIV positive will continue to take the formula to which they were assigned. Neither patients nor their doctors will know which formula they are taking until the study ends. All infants assigned to continue the study treatment beyond the eight week study visit will have study visits at weeks 16, 28 and 52. At week 28, study formula will be discontinued. Infants will start eating other foods when, and as recommended, by their doctors. The study lasts one year.

Required:

- CD4 cell (T-cell) range: not appli cable
- HIV infected mother
- Infants must be less than or equal to two weeks old
- Infants must weigh at least four pounds

Not allowed:

- Infants with congenital conditions that may result in a high probability that the infant will not survive beyond the 28-week treatment period
- Infants takig drugs that alter growth such as megace, corticosteroids or growth hormone
- Any metabolic disorder resulting in malabsorption
- Women who decide to breastfeed

Location:

LAC-USC Medical Center - Maternal Child Program
Melissa Scanlon, RN
(213) 226-5095

164. Herpes Simplex/Zoster Infections in Children: Valacyclovir

Title:

Pediatric ACTG 253: A Phase I Trial to Evaluate the Pharmacokinetics, Safety and Tolerance of Valacyclovir HCl in HIV-1 Infected Children (up to 12 Years of Age) with Herpes Simplex Infections or Varicella/Zoster Infections

Type of treatment:

Valacyclovir: antiviral

Purpose:

To see if valacyclovir is safe and well-tolerated for children with herpes infections. To see how valacyclovir is processed by the body and to see what dose is best for children to take.

About the study:

This is a dose-ranging or dose-escalating study. This means that the first group of children with herpes simplex will receive the lowest dose of valacyclovir. If no bad side effects are observed, the next group of children with herpes simplex will receive a higher dose of valacyclovir. Based on the safety data provided by these two groups, an appropriate dose of valacyclovir will be selected to be studied in children with varicella or zoster. Valacyclovir is a pill and taken by mouth. Study visits are required on days 0, 1, 2, 4, 9 and 40. The study lasts approximately 40 days.

Required:

GENERAL

- HIV positive
- Between 4 and 12 years old
- Children on antiviral therapy must have been on the same therapy for at least two weeks prior to study entry

HERPES SIMPLEX

- CD4 cell (T-cell) range: 100 or more
- Localized herpes simplex infection

HERPES ZOSTER

- CD4 cell (T-cell) range: 100 or more
- Onset of zoster within 72 hours of study entry

HERPES VARICELLA

- CD4 cell (T-cell) range: 250 or more
- Onset of varicella within 48 hours of study entry

Not allowed:

- Any AIDS diagnosis **(varicella patients only)**
- More than 48 hous after onset of lesions **(varicella patients only)**
- More than 72 hours after onset of lesions **(zoster patients only)**
- Children with evidence of zoster dissemination

Location:

UCLA Medical Center - Pediatrics
Leslie Spring
(310) 206-6369

UCSD Treatment Center - Pediatrics
Myrene Preston
(619) 543-8080 ext. 204

165. Measles Vaccine in Children: Measles vaccine

Title:

Pediatric ACTG 225: A Phase II; Comparative Study of Seroconversion of Single-Dose and Two-Dose Measles Vaccination in HIV-Infected and HIV-Uninfected Children: A Multicenter Trial of the Pediatric AIDS Clinical Trials Group

Type of treatment:

Measles Vaccine: vaccine

Purpose:

To compare the seroconversion rates at 13 months of age in HIV-infected and in HIV-uninfected children who receive two doses of measles vaccine to those children who receive a single dose of measles vaccine. To compare the measles seroconversion rates in HIV-infected and HIV-uninfected children.

About the study:

Children who were born to HIV-infected mothers will be assigned by chance to receive one of two measles vaccine schedules; measles vaccine at 6 and 12 months of age or a single vaccine at age 12 months. All children will receive a measles vaccine at age 12 months. Children will enroll in this study at age 6 months and be followed for 24 months after their last vaccination. There are 14 study visits and the study lasts about three years.

Required:

- CD4 cell (T-cell) range: greater than or equal to 750
- Viral load range: not applicable
- HIV positive or negative
- Children 6 months of age but not over 7 months born to HIV-infected mothers
- Children should receive other childhood immunizations (other than measles) according to the recommendations of the American Academy of Pediatrics

Not allowed:

- Children with intercurrent illness and/or fever for seven days. May be rescreened when symptoms resolve
- Known exposure to measles within 14 days of study entry
- Children currently receiving IVIG or who have received any gamma globulin preparation within the previous six months.
- Children who received steroids within four weeks of study entry

Location:

UCLA Medical Center - Pediatrics
Leslie Spring
(310) 206-6369

LAC-USC Medical Center - Maternal Child Program
Melissa Scanlon, RN
(213) 226-5095

UCSD Treatment Center - Pediatrics
Myrene Preston
(619) 543-8080 ext. 204

Children's Hospital, Oakland
Teresa Courville, RN, MN
(510) 428-3885, ext. 2827

166. Varicella Vaccine in HIV-Infected Children: Varicella Vaccine

Title:

Pediatric ACTG 265: Phase I/II Study of Safety and Immunogenicity of Live Attenuated Varicella Vaccine (VARIVAX) in HIV-Infected Children

Type of treatment:

Varicella Vaccine: vaccine

Purpose:

To see if varicella vaccine is safe and effective in asymptomatic or mildly symptomatic HIV-infected children ages greater or equal to 1 year old and less than or equal to 8 years old.

About the study:

All children will receive varicella vaccine at the beginning of the study and at week 12. Those children who have are still negative for varicella at week 52 will receive a third varicella vaccine. There are 15 study visits and the study lasts three years.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: patients must have a minimum of two positive tests between greater than or equal to 1 year old and less than or equal to 8 years old
- Between 12 and 48 months old
- HIV positive
- Category N1 or A1 Clinical/Immunological status

Not allowed:

- Active infection within 72 hours of entry
- Fever greater than 101 within 72 hours of study entry
- Exposure to chicken pox and/or herpes zoster within four weeks prior to study entry
- Past occurrence of chicken pox or herpes zoster
- Any use of steroids within 30 days of study entry
- Treatment with any anti-herpes drug such as acyclovir, famciclovir, valaciclovir, ganciclovir, interferon and foscarnet within one week of study entry
- Use of IVIG, VZIG or blood product receipient within five months of study entry
- Current use of aspirin or expected use within six weeks of immunization
- Receipt of any other vaccine within 30 days of study entry

Location:

LAC-USC Medical Center - Maternal Child Program
Melissa Scanlon, RN
(213) 226-5095

UCSD Treatment Center - Pediatrics
Myrene Preston
(619) 543-8080 ext. 204

Children's Hospital, Oakland
Teresa Courville, RN, MN
(510) 428-3885, ext. 2827

167. HIV Infection in Children and Adolescents: Observational

Title:

Pediatric ACTG 219: Pediatrics Late Outcomes Protocol

Type of treatment:

Observational: none

Purpose:

To learn about the long-term survival and quality of life of infants and children enrolled in ACTG studies. To learn more about the differences between HIV disease progression in HIV+ infants and children, and the effects of anti-HIV drugs in infants and children who are not HIV+.

About the study:

All patients get physical exams and blood tests on a regular basis. Information on health problems and quality of life are also collected. Patients will be in the study until their 21st birthday.

Required:

- CD4 cell (T-cell) range: not specified
- An infant, child or adolescent born to an HIV+ woman who was enrolled in an ACTG study while pregnant, **or**
- HIV+ infant or child ever enrolled in an ACTG treatment study

Not allowed:

- Children enrolled only in ACTG 220 or other observational studies

Location:

UCSF Pediatric Immunology Program
Deborah Trevithick, RN, MS
(415) 476-6480

UCLA Medical Center - Pediatrics
Leslie Spring
(310) 206-6369

LAC-USC Medical Center - Maternal Child Program
Melissa Scanlon, RN
(213) 226-5095

UCSD Treatment Center - Pediatrics
Myrene Preston
(619) 543-8080 ext. 204

Children's Hospital, Oakland
Teresa Courville, RN, MN
(510) 428-3885, ext. 2827

168. HIV Infection in Pregnant Women: Observational

Title:

Pediatric ACTG 255: A Study of Perinatal Transmission of Open Zidovudine-Resistant HIV Among Pregnant Women Treated with Zidovudine

Type of treatment:

Observational: none

Purpose:

To collect information about the effect of long-term AZT treatment on the occurence of AZT-resistant HIV in pregnant women and to see if AZT-resistant women will transmit HIV to their newborn babies.

About the study:

Women enrolling on this study will be asked questions about their medical history, and will be given a physical examination and laboratory tests three times before the birth of their child. After the infants are born, they are given four physical examinations and laboratory tests over the next two years. This is an observational study and patients will not be given drug treatment.

Required:

- CD4 cell (T-cell) range: 300 or below
- HIV positive
- Estimated to be 20-36 weeks pregnant
- At least 13 years old
- Taken AZT for at least six months prior to study entry, including continuous AZT use during current pregnancy

Not allowed:

- Current use of any antiretrovirals other than AZT
- Evidence of any pre-existing fetal malformation

Location:

UCLA Medical Center - Pediatrics
Leslie Spring
(310) 206-6369

Compassionate Use, Expanded Access and Treatment IND Programs

Any new drug must be approved by the Food and Drug Administration (FDA) before it can be prescribed by a physician. FDA approval is based on the results of clinical trials. Many months or even years of clinical trials and analysis of the results may be needed before approval can be granted. Such a long testing period is necessary in order to learn about the safety and effectiveness of the drug. But sometimes, even during fairly early phases of testing, a drug may appear to have benefits which outweigh the risks of taking it before it has been fully tested. This is especially true when people cannot take any of the approved drugs, when approved drugs do not work, or for conditions which have previously been untreatable. Compassionate Use, Expanded Access and Treatment IND are programs which allow patients limited access to promising experimental treatments before they have been given full approval by the FDA. They are developed jointly by the FDA and the pharmaceutical company that makes the drug.

Name of Drug	What Drug is Used For	Company and Name of Program	Telephone
Albendazole	Microsporidiosis	SmithKline Beecham Compassionate Use Protocol	800-877-7074, x6454 (physician calls only)
AmBisome (liposomal Amphotericin-B)	Cryptococcal meningitis failed standard Ampho-B	Fujisawa Pharmaceuticals Compassionate Use Program	847-317-0600 (physician calls only)
Azithromycin (Zithromax)	Toxoplasmosis Cryptosporidiosis Disseminated MAC	Pfizer Compassionate Use Protocol Pfizer Compassionate Use Protocol Pfizer Compassionate Use Protocol	800-742-3029 800-742-3029 800-742-3029
ddC (zalcitabine, HIVID)	HIV Infection (pediatric)	Hoffmann-LaRoche Open Label Program	800-285-4484
Mitoguazone dihydrochloride (MGBG)	Non-Hodgkin's Lymphoma refractory or relapsed	Ilex Compassionate Use Program	210-677-8000
Nevirapine (Viramune)	HIV Infection CD4 count $\leq$ 200/mm^3 Pediatrics only	Boehringer-Ingelheim	800-595-5494
Nitazoxanide (NTZ)	*Cryptosporidium*	Unimed Pharmaceuticals Compassionate Use Protocol	800-864-6330 ext 3032
Sparfloxacin (Cinarcid)	Multidrug resistant TB	Rhone-Poulenc Rorer Compassionate Use Protocol	800-727-6737
Spiramycin	Chronic diarrhea caused by *Cryptosporidium*	Rhone-Poulenc Rorer Compassionate Use Protocol	800-727-6737
Thalidomide (Synovir)	Wasting syndrome Apthous ulcers	Celgene	800-253-1596

California AIDS Drug Assistance Program

The California AIDS Drug Assistance Program (ADAP) was established to provide drugs to individuals who otherwise could not afford them. Individuals are eligible for ADAP if they (1) have an adjusted gross income below $50,000 per year, (2) have a valid prescription from a California-licensed physician, and (3) the drugs they need are not covered by Medi-Cal or other third-party payer. An individual is subject to a co-payment if his/her annual adjusted gross income is between 400% of poverty level and $50,000. Individuals with an annual gross income below 400% of poverty level receive the drugs free of charge.

For more information about ADAP call the California Office of AIDS at **916-327-6784**. County and local offices in California are listed on the next page. Other States have similar programs.

California AIDS Drug Assistance Program - Covered Drugs

Common Name	Other Names	Used for
3TC	Lamivudine, Epivir	antiretroviral
AZT	ZDV, Retrovir, zidovudine	antiretroviral
Acyclovir	Zovirax	antiviral
Amphotericin B	Fungizone	antifungal
Atovaquone	Mepron	antibacterial
Azithromycin	Zithromax	antibacterial
Bleomycin sulfate	Bleonoxane	chemotherapy
Cidofovir	HPMPC, Vistide	antiviral
Clarithromycin	Biaxin	antibacterial
Clindamycin	Cleocin	antibacterial
Clofazimine	Lamprene	antimycobacterial
Cyclophosphamide	Cytoxan	chemotherapy
Dapsone		antibacterial
d4T	Zerit, stavudine	antiretroviral
ddC	Zalcitabine, Hivid	antiretroviral
ddI	didanosine, Videx	antiretroviral
Delavirdine	Rescriptor	antiretroviral
Dexamethasone	Decadron	corticosteroid
Doxorubicin	Adriamycin	chemotherapy
Dronabinol	Marinol	appetite stimulant
Erythropoietin	EPO, Epres, EPOGEN, Procrit	red blood cell stimulator
Ethambutol	Myambutol	antimycobacterial
Fluconazole	Diflucan	antifungal
Flucytosine	5FC	chemotherapy
Foscarnet	Foscavir	antiviral
G-CSF	Filgrastim, Neupogen	white blood cell stimulator
Ganciclovir, IV	DHPG, Cytovene, Ganciclovir	antiviral
Indinavir	Crixivan	antiretroviral, protease inhibitor
Invirase	Saquinavir	antiretroviral, protease inhibitor
Interferon, alpha	IFN, alpha IFN, Wellferon, Roferon-A, Intron-a, Interferon-alpha	immune modulator
Itraconazole	Sporanox	antifungal
Ketoconazole	Nizoral	antifungal
Leucovorin	Wellcovorin, Folinic acid	white blood cell protector
Liposomal daunorubicin	DaunoXome	chemotherapy
Megace	Megestrol acetate	appetite stimulant
Methotrexate	MTX, Reumatrex	chemotherapy
Mycelex	Clotrimazole	antifungal
Nevirapine	Viramune	antiretroviral
Nelfinavir	Viracept	antiretroviral
Nystatin	Mycostatin	antifungal
Paromomycin	Humatin	antiparasitic
Pentamidine, aerosolized	Nebupent, Pentaire, Aeropent	antiparasitic (PCP)
Prednisone	Deltasone, Prednicen-M, Sterapred	steroid
Pyrimethamine	Daraprim	antibacterial
Rifabutin	Mycobutin	antimycobacterial
Ritonavir	Norvir	antiretroviral, protease inhibitor

California AIDS Drug Assistance Program - Covered Drugs

Common Name	Other Names	Used for
Sulfadiazine	Microsulfon	antibacterial
Trimethoprim	Trimpex, Proloprim	antibacterial
Trimethoprim-Sulfamethoxazole	Bactrim, TMP-SMX, Septra	antibacterial
Trimetrexate glucuronate	NeuTrexin	antibacterial
Vinblastine	Velban	chemotherapy
Vincristine	Oncovin, Vincasar	chemotherapy

County and Local Contacts for AIDS Drug Assistance Program in California

Alameda County Health Dept.
(510) 667-3937

City of Berkeley
(510) 644-6022

Butte County
(916) 895-0462

Contra Costa County
Bud Getty
(510) 313-6602

Del Norte County
(707) 464-3191

El Dorado County
(916) 573-3155

Fresno County
(209) 445-3434

Glenn County
(916) 934-6588

Humboldt County
(707) 441-2045

Imperial County
(619) 339-4448

Kern County
(805) 861-3644, x366

Kings County
(209) 584-1401, x4528

Lake County
(707) 263-2241

Lassen County
(916) 251-8183

Long Beach
Rose Gutierrez
(562) 570-4316

Los Angeles County
(213) 351-8084

Madera County
(209) 675-7627

Marin County
(415) 499-3624

Mendocino County
(707) 463-4573

Merced County
(209) 385-7700 x6170

Monterey County
(408) 759-7272 (NIDO Clinic)
(408) 394-4747 (Seaside)
(408) 772-8200 (Salinas)

Napa County
(707) 253-4570

Nevada County
(916) 477-5551

Orange County
(714) 834-8175 or
(714) 834-8241

City of Pasadena
(818) 844-6000

Placer County
(916) 889-7175

Plumas County
(916) 283-6330

Riverside County MIA Program
(909) 358-6453

Sacramento County
(916) 732-9183

San Benito County -- No ADAP Clients should be referred to Monterey County ADAP Program

San Bernardino County
(909) 383-3036 or
(909) 386-8112

San Diego County
(619) 236-2479

San Francisco County
(415) 554-9168

San Joaquin County
(209) 468-2328

San Luis Obispo County
(805) 781-3660

San Mateo County
(415) 573-2188

Santa Barbara County
(805) 681-5303

Santa Clara County
(408) 299-6150

Santa Cruz County - No ADAP Clients should call Sacramento
Trice Salveson
(916) 327-6779

Shasta County
(916) 247-3338

Siskiyou County
(916) 841-4062

Solano County
(707) 553-5117

Sonoma County
(707) 524-7402

Stanislaus County
(209) 525-7336

Tehama County
(916) 527-6824

Tulare County
(209) 685-2535

Tuolumne County
(209) 533-7400, x7412

Patient Assistance Programs

Some pharmaceutical companies have programs that provide free or lower cost medications to patients who could not otherwise pay for them. Each program has specific requirements about who is eligible and what kind of financial help is available. If you need help paying for any of the drugs listed below, talk to your doctor. He or she will need to call the coordinators of the appropriate program(s) and give them information about your financial status and prescription drug needs.

Name of Drug	What Drug is Used For	Company and Name of Program	Telephone
Amplicor Viral Load Testing	HIV viral load	Roche Diagnostics	888-837-8727
Chiron bDNA Viral Load Testing	HIV viral load	Chiron Laboratories	888-448-5623
3TC (Lamivudine, Epivir)	HIV Infection	Glaxo Wellcome Co. HIV Patient Assistance Program	800-513-3028
Acyclovir (Zovirax)	Herpes simplex, Herpes zoster	Glaxo Wellcome Co. HIV Patient Assistance Program	800-513-3028
Alpha Interferon-2A recombinant (Roferon-A)	Kaposi's Sarcoma (>200 T-cells) anogenital neoplasms	Hoffmann-LaRoche, Inc. Oncoline (Reimbursement assistance and literature search) Indigent Patient Program	 800-443-6676 800-285-4484
Alpha Interferon-2B recombinant (Intron A)	Kaposi's Sarcoma anogenital neoplasms	Schering-Plough Corp. Commitment to Care	800-521-7157
Amphotericin B Lipid Complex (ABELCET)	Life threatening fungal infections	Liposome Co. Indigent Patient Program	 800-335-5476
Amphotericin B oral suspension (Fungizone)	Fungal Infections	Bristol-Myers Squibb	800-272-4878
Atovaquone (Mepron)	PCP treatment	Glaxo Wellcome Co. HIV Patient Assistance Program	800-513-3028
AZT (zidovudine, Retrovir)	HIV infection	Glaxo Wellcome Co. HIV Patient Assistance Program	800-513-3028
Azithromycin (Zithromax)	Toxoplasmosis, MAC	Pfizer Inc. Premiere Research	800-869-9979
Cidofovir (Vistide)	CMV Retinitis	Gilead Sciences	800-445-3235
Cimetidine (Tagamet)	Ulcers	SmithKline Beecham, Access To Care	800-546-0420
Ciprofloxacin (Cipro)	Bacterial Infections	Bayer Indigent Patient Program	800-998-9180
Clarithromycin (Biaxin)	MAC	Abbott Laboratories Physician calls only	800-688-9118
Clindamycin	PCP treatment	Upjohn Co. Patient Assistance Program	800-242-7014
Clofazimine	MAC Treatment/Prevention	Novartis Pharmaceuticals Patient Assistance	800-257-3273
Compazine	Nausea	SmithKline Beecham Access To Care	800-546-0420
Crixivan (Indinavir)	HIV Infection	Merck Pharmaceuticals	800-850-3430

Patient Assistance Programs

Name of Drug	What Drug is Used For	Company and Name of Program	Telephone
DaunoXome (liposomal daunorubicin)	KS	NeXtar Pharmaceuticals	800-226-2056
Delavirdine (Rescriptor)	HIV Infection	Pharmacia-Upjohn	800-711-0807
ddC (zalcitabine, HIVID)	HIV infection	Hoffman-La Roche, Inc. Oncoline	800-285-4484
ddI (didanosine, Videx)	HIV Infection	Bristol-Myers Squibb Videx Assistance Program	800-472-4878
d4T (stavudine, Zerit)	HIV Infection	Bristol-Myers Squibb Patient Assistance Program	800-472-4878
DOXIL	Kaposi's Sarcoma	SEQUUS Pharmaceuticals Patient Assistance Program	800-375-1658
Dronabinol (Marinol)	Appetite stimulant	Roxane Laboratories Patient Assistance Program	800-274-8651
EPO (erythropoietin, Procrit)	AZT-related anemia	Ortho Biotech Procrit Financial Assistance Program	800-553-3851
Ethambutol (Myambutol)	TB treatment, MAC treatment	Wyeth-Ayerst Lederle Labs Patient Assistance	800-568-9938
Fluconazole (Diflucan)	Fungal infections	Pfizer Inc. Diflucan patient assistance program	800-869-9979
Foscarnet (Foscavir)	CMV disease, acyclovir-resistant HSV	Astra Pharmaceuticals Foscavir Assistance	800-488-3247
Ganciclovir (Cytovene)	CMV disease	Roche-Syntex Laboratories Provisional Assistance Programs	800-282-7780
Ganciclovir (oral)	CMV retinitis	Roche BioScience - physicians only	800-282-7780
Ganciclovir implant (Vitrasert)	CMV retinitis	Chiron Vision Patient Assistance Program	800-843-1137
G-CSF (Neupogen)	AZT-related neutropenia	Amgen, Inc.	800-272-9376
GM-CSF (Leukine)	AZT-related neutropenia	Immunex Corporation (Physician calls only)	800-334-6273
Human Growth Hormone rHGH Serostim	HIV Wasting Syndrome	Serono Laboratories	800-714-2437
Hydroxyurea (Hydrea)	HIV infection	Bristol-Myers Squibb	800-272-4878
Itraconazole (Sporanox)	Histoplasmosis, Fungal infections	Janssen Pharmaceutica Patient Assistance Program	800-544-2987
Ketoconazole (Nizoral)	Fungal infections	Janssen Pharmaceutica Patient Assistance Program	800-554-2987
Megestrol Acetate (Megace)	HIV-related Wasting	Bristol-Myers Squibb Patient Assistance Program	800-272-4878
Mycelex	Oral Candidiasis (thrush)	Bayer Indigent Patient Program	800-998-9180
Nelfinavir (Viracept)	HIV Infection	Agouron Pharmaceuticals	888-777-6637

Patient Assistance Programs

Name of Drug	What Drug is Used For	Company and Name of Program	Telephone
Nevirapine (Viramune)	HIV Infection	Boehringer-Ingelheim	800-274-8651
Octreotide Acetate (Sandostatin)	Wasting	Novartis Indigent Patient Program	888-455-6655
Oxandrolone (Oxandrin)	Wasting	BTG Pharmaceuticals	800-741-2698
Paromomycin (Humatin)	Cryptosporidiosis	Parke-Davis Patient Asistance	800-223-0432
Pentamidine (Nebupent)	PCP Prophylaxis	Fujisawa, USA, Inc.	800-888-7704, x8607
Pentoxifylline (Trental)	HIV Infection, KS, Dementia	Hoechst Marion Roussel Inc. Indigent Patient Program	800-552-3656
Pyrimethamine (Daraprim)	Toxoplasmosis	Glaxo Wellcome Co. HIV Patient Assistance Program	800-513-3028
Rifabutin (Mycobutin)	MAC	Pharmacia Upjohn Inc.	800-366-5570
Ritonavir (Norvir)	HIV Infection	Abbott Labs Temporary Assistance Program (Physicians only)	800-659-9050
Saquinavir (Invirase)	HIV Infection	Hoffman-LaRoche, Inc. Patient Assistance Program	800-272-7780
Streptomycin	TB Treatment	Pfizer, Inc. Patient Assistance Program	800-254-4445
Testosterone (Testoderm patch)	Wasting	Alza Pharmaceuticals	800-321-3130 ext. 2287
TMP/SMX (Septra)	PCP prophylaxis and treatment	Glaxo-Wellcome HIV Patient Assistance Program	800-513-3028
TMP/SMX (Bactrim)	PCP prophylaxis and treatment	Hoffman-La Roche Inc., Patient Assistance	800-285-4484
Trimetrexate (Neutrexin)	PCP treatment	US Bioscience Patient Assistance	800-887-2467
WinRho SD	Thrombocytopenia	Univax Biologics	800-789-2099

Common Questions about Clinical Trials

What is a clinical trial?

A new drug goes through many tests in the lab before people take it. If the results are good, the drug is tested in small groups of people. When people take a new drug as part of a study, it is called a clinical trial.

The results of a clinical trial are very important. They tell us about the safety of the drug when people take it. They also tell us if the drug helps people get better.

Why should I join? What do I get out of this?

Here are some of the reasons to join a clinical trial:

- The treatment being tested may work for you.
- Clinical trials may be the only way to get a promising new drug.
- Drugs taken as part of a clinical trial are usually free. (Even if a drug you want to take is available on the "under ground," or by prescription, you may not be able to afford it).
- You can help speed the development of new treatments for HIV.

Will I be used as a "guinea pig"?

Before you join a clinical trial, you should understand what will happen during the study and what the researchers hope to learn. When you join a clinical trial, you volunteer of your own free will. Even though you signed a consent form, you have the right to quit at any time.

In most cases, you join a clinical trial because you already have a disease and you think the drug being tested may help you. Sometimes, you may join a clinical trial while you are still healthy, in the hope that the treatment may prevent you from getting sick.

What if the drug makes me sicker?

The researchers who design the trials always plan what to do if a volunteer gets ill from the drug they are studying. If the drug makes you sicker, you may have to take a lower dose, or stop taking the drug completely. In some trials, you might be switched to another drug. You should keep in close contact with your doctor as well as the researchers so they can treat any side effects as soon as possible.

Will I have to take a placebo ("sugar pill")?

Placebos are usually used only when no effective treatment is known. In these cases a "placebo-controlled" study is the only reliable way to find out if a drug works. Some patients are asked to take placebos so researchers can learn whether changes in health are caused by the drug, or would have happened without treatment.

Patients who take placebos get the same medical attention as people who get the study drug. Usually, all patients in the study are offered the active drug if it is shown to be safe and effective.

How can I tell which trial might be good for me?

The more you know about your own health status and about HIV disease, the easier it will be for you to make decisions about what trials may be good for you. You should always talk to your doctor or health care provider to get their opinions, too. We list contact names and numbers for the trials included in this directory so you or your doctor can get more information about trials you are interested in.

What are my rights as a patient?

The people involved in your care must treat you with consideration and respect. You have the right to:

- be told all the important details about your care
- ask questions and have them answered
- say no to any test, procedure or medication
- go to another health care provider to get more information
- know the names of anyone you talk to
- read your medical records with your health care provider
- make your own decisions about your health care
- know that your medical records will be kept confidential

What are my responsibilities as a patient?

The researchers have a right to expect certain things from you, too. As a patient, you have the responsibility to:

- be honest about your medical history and anything in your lifestyle which may affect your health
- follow instructions and take the study drug(s) as requested
- keep appointments or re-schedule them in advance
- report any changes in your health
- be sure you understand the facts before you make a complaint

What is informed consent?

Researchers are required by law to give you all the facts about a study before you join. This information must be explained in a way that you can understand. Before you join a study, you will be asked to read and sign a consent form. This is called giving ***informed consent***.

When you sign the consent form, it means that you have been given all the information about the study, and that you agree to join. The consent form is not a contract. You do not give up any rights if you sign the consent form. You can leave the study at any time.

What should I know before I sign the consent form?

Before you sign the consent form, you should know:

- the reasons for using the experimental treatment
- the risks and benefits of taking part in the study
- if there are any extra costs, doctor visits, lab tests, etc.
- what drugs you will have to take

Are there any other questions I should ask before I sign the consent form?

Before you decide to join a trial, you may want to know:

- How will information about me be handled to protect my privacy?
- Can I take the drug after the trial is over? Will I have to pay for it?
- If I get sick or develop health problems while on the trial, will I be taken off the trial?
- How can I find out the results of the trial?
- Are there other studies of this drug I should know about?
- Do I have to use birth control? If so, what kind? If I become pregnant will I have to leave the study?

What should I do if I don't understand something?

Do not sign the consent form until you understand everything in it. Keep asking questions. The staff should be able to answer most of them. However, there may not be enough information about certain drugs to answer some questions.

Why do some studies pay people to participate?

Some research studies pay people who volunteer to participate in them. Usually, studies only pay when there is no expected medical benefit to participants, such as when a new drug is being tested for only a short amount of time. Sometimes studies pay when they ask a lot of time and energy from participants, such as overnight stays in the hospital, or long surveys about personal issues.

Some researchers feel that the offer of money is not always ethical because it may tempt some people to take risks that they would not take otherwise. Ask and understand why the study is paying participants before you decide whether to join. Keep in mind that studies that pay usually do not pay until the study is over.

When studies do not pay, it is because the potential benefit of the study is felt to be enough compensation for the effort and risk of participating in it. If a study gives you free medication, check-ups, lab tests and helps you to be healthier by curing or preventing disease, then you *do* get something out of your participation.

Getting more information about specific studies

If you want to find out more about a specific clinical trial, call the person listed under "Location" for that trial. This is usually a research nurse or study coordinator. S/he will ask you some questions about your health to find out if you fit the entry criteria for the trial. It is a good idea to have a copy of your most recent laboratory tests, such as blood tests and T-cell counts, when you call.

Finding out if you're eligible: The screening visit

If the research nurse thinks you may be eligible, s/he will ask you to come in for a "screening" visit. At this visit, someone will explain the study to you, and you will give them more information about your health and your medical history. You may also have a brief physical exam and have some blood tests done.

Giving "informed consent"

If you meet all the entry criteria you will be asked to sign a consent form. When you sign the consent form it means that you have been given all the information about the study, and that you agree to participate.

The first study visit

After you have signed the consent form, you can join the study during a "baseline" visit—the first official visit of the study. A lot of information is collected during the baseline visit, so it may take longer than your regular office visit.

Followup visits

If you are taking a new drug, you will probably be asked to come back to the office for another visit in 1 - 2 weeks. This is to watch for any side effects of the drug that you may be experiencing. If everything seems to be all right, you will be asked to come back for regular followup visits. Frequency of visits may vary from daily to every few months, depending upon the study.

Keeping in touch

It is important to come to each study visit, and to let the researchers know how you are doing. It's also important to keep seeing your regular health care provider. Everyone is interested in protecting your health and safety when you are in a clinical trial, so it is important to stay in touch.

There are a number of misunderstandings about women and clinical trials. Here are the facts about some of the most common misunderstandings.

Can women with HIV join clinical trials?

Yes. Every clinical trial has requirements about who can join. If a woman meets these requirements, she can join. Most clinical trials are open to both women and men.

Women often don't get enough information about clinical trials and think that they cannot join simply because they are women.

Check the index of this Directory for studies that are open only to women, but remember that women may also join nearly all of the other studies listed.

Are there special rules about birth control and pregnancy?

Yes. In many studies, women must agree to use birth control if they have sex with men. Pregnant or nursing women usually can't join a trial of an untested drug because it is not known if the drug might harm the baby. However, there are now a few studies for pregnant women.

What happens if a woman becomes pregnant while in a trial?

A woman should know the rules about pregnancy before she joins a trial. Different trials have different rules about whether a woman can continue in the trial if she becomes pregnant.

Some women think they must have an abortion if they become pregnant while in a study. This is not true. Every woman always has the right to make her own decisions about pregnancy. No one can force you to have an abortion. However, if you choose to have the baby, it may affect your continued participation in the trial.

If you become pregnant, you may want to talk to the contact people for the studies for children listed in this guide (pages 80-86). These people are usually experts in pregnancy and women with HIV and can give you the most current information.

Services for women with HIV -- Los Angeles Area

There are too many programs and services for women in the Los Angeles area to list here. To receive a full listing, contact AIDS Project Los Angeles for a free copy of their guide to LA resources.

AIDS Project LA (213) 993-1459 (English)

(213) 993-1483 (Spanish)

Services for women with HIV -- San Diego Area

Being Alive has programs for women and children, including treatment education and advocacy.

San Diego: (619) 291-1400 or 1-800-606-2224

Services for women with HIV -- Northern California

WORLD (Women Organized to Respond to Life-Threatening Diseases). These women publish a newsletter with treatment information, and organize classes to teach themselves about HIV, including information on clinical trials. They can also offer referrals to services in the Bay Area.

You may contact WORLD at (510) 658-6930.

Check the Resources section on page 121 for more resources of interest to women.

Most trials for adults do not allow children under the age of 13 to join. But there are clinical trials designed especially for children from birth to age 13 or older. Children's research is done by doctors and nurses who are experts on children's bodies and health.

Why are there trials for children only?

Children's bodies are different from adults' bodies, and HIV affects children differently than adults. For example, children get certain infections more frequently than adults, and never get some infections that adults get. It is important that your child see a doctor who knows about both HIV and children.

Because children's bodies are different from adults', a drug may work differently in children. Some drugs work very well in children and not at all in adults. A child usually needs a lower dose of a drug. Some drugs are too strong to give to children or have side effects that are worse for children than adults. Because of these differences, most researchers feel that it is better to test drugs separately in children.

Is it ethical to do research with children?

Some people think that it is never right to do research with children because children are too young to decide for themselves to take part in research. They feel it is not fair to put children at risk. Others feel that with AIDS and other life-threatening diseases that don't have a cure, the risk of the disease is greater than the risk of taking a drug that hasn't been thoroughly tested. Research may be the only chance to get certain drugs, and these drugs may be the only hope of getting better.

A child's parent or guardian must give written permission before a child can join a clinical trial. This permission is called ***"informed consent"***.

Where can I find out more about clinical trials for children with HIV?

This Guide lists trials for children at the end of the clinical trials section beginning on page 81.

You can call the contact people for the studies listed there—these people are usually medical experts on children with HIV and should be able to answer your questions.

What does "youth" mean?

People use the term "youth" differently. It can mean people from 13 to 18 years old, or 13 to 21 years old, or 13 to 26 years old. Other words used for youth are "adolescent" and "teen."

Why are youth treated differently in clinical trials?

Youth are different physically and emotionally from both children and adults. Healthcare and support programs for youth take these differences into account.

In which trials may youth participate?

Most clinical trials allow youth to join. Often people between ages 13 and 18 are eligible for both children's and adults' clinical trials. We list age restrictions for all the trials in this directory.

Do youth under 18 need permission to join a clinical trial?

Yes, minors (younger than 18 years old) need to get written permission from a parent or guardian to join a drug trial, even if they get medical care at a clinic without permission. There are people working to change the laws in this area, and they may be able to help you join a trial without your parents' permission in certain situations. See the "Common Questions" section of this Directory for an explanation of what it means to give ***"informed consent."***

Youth and Clinical Trials

Medical & Referral Services for Youth with HIV—Northern California

Bay Area Young Positives (BAY Positives)
Antigone Hodgkins, Executive Director
518 Waller Street
San Francisco, CA 94117
(415) 487-1616

BAY Positives is an education, support and advocacy organization by and for young people with HIV from the entire Bay Area.

Project AHEAD
Clark Moore, Director
1242 Market Street, 3rd Floor
San Francisco, CA 94102
(415) 487-5777
Project Ahead provides information to HIV+ youth and their providers about clinical trials.

Larkin Street Medical Clinic
1044 Larkin Street (at Sutter Street)
(415) 673-0911
Free medical and support services for homeless and runaway youth ages 12 to 23.

UCSF Teen Clinic
400 Parnassus, 2nd Floor, Room A270
(415) 476-8626 (Dave Knopf)
Full medical and support services.

San Francisco General Hospital
1001 Potrero Avenue (between 22nd and 23rd Streets)
Teen and Adolescent Clinic (under 18 years old)
(415) 206-8376

Kaiser Teenage Clinic
2350 Geary Boulevard, 1st Floor
(415) 202-2213
Medical and support services for youth who have Kaiser insurance or MediCal.

Medical & Referral Services for Youth with HIV—Southern California

Childrens Hospital LA
Risk Reduction Program
5000 Sunset Boulevard, 4th Floor, LA, CA 90027
(213)669-2390
Free health care and treatment ot young people with HIV between the ages of 12 and 24. Case management, psychosocial and nutritionsal education services also available.

High Risk Youth Program: (213) 669-2503
4650 Sunset Boulevard #2
Los Angeles, CA 90027
Medical services for homeless youth.
Department of Adolescent Medicine: (213) 660-2450
This department has several open or about to open studies designed especially for youth. Some of these are "natural history" studies that are trying to learn about young people with HIV and their situations and needs. Call and participate!

LA County USC Medical Center: 5P21 Clinic
1300 North Mission Rd., LA, CA 90033
(213) 343-8255
Adult, maternal and pediatric care and medical services.

Youth HIV Project
5000 Sunset Boulevard, 4th Floor, LA, 90027
(213) 669-2390
Free medical crae for HIV infected youth 12 to 20 years old, support groups, case management, health education.

Children's Hospital and Health Center
3020 Children's Way
San Diego, CA 92123
(619) 576-1700

Injection Drug Users and Clinical Trials

Injection drug users and people who use illegal street drugs, such as heroin, crack and speed, have often been left out of clinical trials. There are several reasons for this.

Street drugs can cause damage to the liver or kidneys. If your liver or kidneys are already damaged, taking a study drug might cause even more harm. Some trials have complicated rules that participants must follow. Researchers may think that if you use drugs you won't show up for your clinic visits, or won't take the study drugs as directed.

Most of the clinical trials in this directory ***do not*** exclude people just because they have used illegal drugs. If you are told you cannot join a clinical trial, ask the reason why. If you are (or were) an injection drug user, one of the following reasons may explain why you cannot join the trial.

Damaged liver or kidneys

Doctors can use certain laboratory tests to find out if your liver and kidneys are healthy. This is important, because you can have harmful side effects from the study drug if your liver or kidneys are damaged. These tests are usually done during the "screening" visit. If any of the tests are "outside normal limits," you may not be able to join the trial. This is done to protect your health.

Dangerous drug interactions

It can be very dangerous to mix some drugs, or to mix drugs and alcohol. Even mixing methadone with some study drugs can be dangerous. It is important to let your doctor and the researchers know ***every*** drug you are taking, to prevent harmful side effects.

Unable to comply with the "rules" of the study

Some trials have very complicated rules, and some people find it hard to follow them. That is why, if your doctor thinks you are "unreliable," you may not be able to join a clinical trial. If you do not take the study drug as directed, or frequently miss clinic appointments, it may be impossible to learn if the drug is working, or to prevent harmful side effects.

AIDS Community Research Consortium
1048 El Camino Real, Suite A
Redwood City, CA 94063
(650) 364-6563

AIDS Healthcare Foundation
1300 N. Vermont Ave., Suite 502A
Los Angeles, CA 90027
(213) 913-3953

AIDS Oncology Practice at UCSF/Mt. Zion
2356 Sutter Street, 5th Floor Pavilion
San Francisco, CA 94115
(415) 567-5581

AIDS Research Alliance
621-A North San Vicente Blvd.
West Hollywood, CA 90069
(310) 358-2429

AIDS Research Center/Dept. of Veteran Affairs
3801 Miranda Avenue
Palo Alto, CA 94304
(650) 493-5000

Bay Area Perinatal AIDS Center (BAPAC)
1001 Potrero Avenue, Room 6D1
San Francisco, CA 94110
(415) 206-8919

Beer Medical Group
5901 West Olympic Boulevard, #420
Los Angeles, CA 90036
(213) 937-5151

Beer Medical Group - North Hollywood
12626 Riverside Drive, Suite 510
North Hollywood, CA 91607
(818) 980-5107

California Clinical Trials Medical Group
8500 Wilshire Boulevard, 7th Floor
Beverly Hills, CA 90211
(310) 854-4949

California Partners Study
UCSF Dept. of OB/GYN
74 New Montgomery, Suite 400
San Francisco, CA 94105-3411
(800) 262-2430

Cedars-Sinai Medical Center
Division of Infectious Diseases
8700 Beverly Boulevard, #B-226
Los Angeles, CA 90048
(310) 855-3755

Center for Special Immunology - Irvine
100 Pacifica, Suite 100
Irvine, CA 92718
(714) 753-0670

Center for Special Immunology - Beverly Hills
8920 Wilshire Blvd., Suite 500
Beverly Hills, CA 90211
(310) 289-6020

Children's Hospital, Oakland
747 - 52nd Street
Oakland, CA 94609
(510) 428-3337

Community Consortium
(See page 119 for a list of participating sites and providers)
3180 18th Street, #201
San Francisco, CA 94110
(415) 476-9554

Community Eye Medical - Brian G. Terry, MD
301 S. Fair Oaks Avenue, #104
Pasadena, CA 91105
(818) 287-2000

Davies Medical Center HIV Institute
Castro and Duboce
San Francisco, CA 94114
(415) 565-6660

Clinical Trials Sites

Desert Hospital Comprehensive Cancer Center
1180 N. Indian Canyon, Suite E320
Palm Springs, CA 92262
(760) 416-4733

East Bay AIDS Center
3031 Telegraph Avenue, Suite 235
Berkeley, CA 94705
(510) 204-1870

HIVCare, Saint Francis Memorial Hospital
900 Hyde Street
San Francisco, CA 94109
(415) 353-6215

Harbor-UCLA Medical Center
1124 W. Carson Blvd.
REI N-24
Torrance, CA 90502
(310) 222-3848

Kaiser Permanente - Los Angeles
1505 North Edgemont, 2nd Floor
Los Angeles, CA 90027
(213) 783-8172

Kaiser San Francisco - HIV Research Unit
2590 Geary Boulevard
San Francisco, CA 94115
(415) 202-3480

Kaiser San Francisco - Opthalmology
1635 Divisadero Street, Suite 400
San Francisco, CA 94115
(415) 202-3980

Kraus Medical Partners
5901 W. Olympic Boulevard, Suite 310
Los Angeles, CA 90036
(213) 930-2324

LAC-USC Medical Center
1300 North Mission Rd.
Los Angeles, CA 90033
(213) 343-8288

LAC-USC Medical Center - Maternal Child Program
1640 Marengo Avenue
HRA Bldg., 3rd Floor
Los Angeles, CA 90033
(213) 226-5068

LAC-USC Medical Center - Norris Cancer Hospital
1441 Eastlake Ave., Room 3016 MS 34
Los Angeles, CA 90033
(213) 226-4578

Lyon-Martin Women's Health Services
1748 Market Street, Room 201
San Francisco, CA 94102
(415) 565-7672 ext. 313

Marcus Conant, MD Clinical Research
350 Parnassus Avenue, Suite 808
San Francisco, CA 94117
(415) 661-2613

Marin County Specialty Clinic
250 Bon Air Road
Greenbrae, CA 94904
(415) 499-7377

Pacific Oaks Research Group
8641 Wilshire Boulevard, Suite 305
Beverly Hills, CA 90211
(310) 360-8800

Paul Norwood, MD, FACP
1313 East Herndon Avenue, Suite 106
Fresno, CA 93720
(209) 261-0990

Quan Yin Healing Arts Center
1748 Market Street
San Francisco, CA 94114
(415) 861-4964

Quest Clinical Research, San Francisco
2300 Sutter Street, Suite 202
San Francisco, CA 94115
(415) 353-0800

Retina-Vitreous Group-David Boyer, MD
8641 Wilshire Blvd., Suite 210
Beverly Hills, CA 90211
(310) 854-6201

St. Luke Medical Group & Clinical Trials
1855 1st Avenue, Suite 300A
San Diego, CA 92101
(619) 235-4211

San Francisco General Hospital Dermatology
SFGH 4M70
San Francisco, CA 94110
(415) 206-8680

San Francisco General Hospital GI Clinic
1001 Potrero Avenue, Room 3C
San Francisco, CA 94110
(415) 206-8824

San Mateo County AIDS Program
3700 Edison Street
San Mateo, CA 94403
(415) 573-2588, 415-573-2385

Santa Clara Valley Medical Center
Early Intervention Project
976 Lenzen Avenue
San Jose, CA 95126
(408) 885-4316

Shared Medical Research Foundation
5620 Wilbur Avenue
Tarzana, CA 91356
(818) 345-2172

Stanford University Medical Center
Center for AIDS Research
300 Pasteur Drive, Room S-156
Stanford, CA 94305
(650) 723-6231

Summit Medical Center Adult Immunology Clinic
3012 Summit Street, 6th Floor
Oakland, CA 94609
(510) 869-6514

Tower Infectious Diseases
8631 West Third Street, Suite 1015E
Los Angeles, CA 90048
(310) 358-2300

UC Davis Cancer Center
4501 'X' St., G-126
Sacramento, CA 95817
(916) 734-3604

UC Davis Medical Center
Division of General Medicine
2221 Stockton Boulevard, Room 3107
Sacramento, CA 95817
(916) 734-7004

UC Irvine - Opthalmology
2000 Medical Plaza Drive, Suite 2004
Irvine, CA 92697
714-824-8303

UC Irvine Medical Center
101 City Drive South, Building 53
Route 81
Orange, CA 92668
(714) 456-7612

UCLA CARE Center
18033 Le Conte Avenue
BH-412 CHS
Los Angeles, CA 90095
(310) 206-6414

UCLA - Jules Stein Eye Institute
100 Stein Plaza, Room 3-110
Los Angeles, CA 90095-7000
(310) 794-7868

UCLA Medical Center - Pediatrics
10833 Le Conte Avenue
Los Angeles, CA 90095
(310) 206-6369

UCSD Treatment Center
2760 - 5th Avenue
San Diego, CA 92103-6325
(619) 543-8080, ext. 238

Clinical Trials Sites

UCSD Treatment Center - Pediatrics
2760 - 5th Avenue
San Diego, CA 92103-6325
(619) 543-8080 ext. 261

UCSF AIDS Clinic
400 Parnassus Avenue, 5th Floor
San Francisco, CA 94143
(415) 476-3226

UCSF AIDS Program at SFGH / ACTU
995 Potrero Avenue, Building 80, Ward 84
San Francisco, CA 94110
(415) 476-9296, ext. 354

UCSF AIDS Program at SFGH/ICTG
995 Potrero Avenue, Building 80, Ward 87
San Francisco, CA 94110
(415) 476-9296, ext. 310

UCSF Center for AIDS Prevention
Changes Project
74 New Montgomery Avenue, Suite 600
San Francisco, CA 94105
(415) 597-9165

UCSF Drug Research Center at SFGH
1001 Potrero Avenue, Building 100, Room 157
San Francisco, CA 94110
(415) 476-5906

UCSF General Clinical Research Center
P.O. Box 1353
San Francisco, CA 94143
(415) 476-3670

UCSF Infectious Diseases Research
505 Parnassus Ave, Room AC30B
UCSF Box #0919
San Francisco, CA 94143
(415) 476-2308

UCSF Pediatric Immunology Program
505 Parnassus Avenue, Room M679
San Francisco, CA 94143
(415) 476-9373

UCSF/SFGH Dermatology
400 Parnassus, 3rd Floor
San Francisco, CA 94143
(415) 476-9219

UCSF/SFGH Endocrinology
1001 Potrero Avenue, Building 100, Room 321
San Francisco, CA 94110
(415) 206-4090

UCSF / Veterans Administration Dept. of Psychiatry
4150 Clement Street
Psych. Services, 116R
San Francisco, CA 94121
(415) 476-7650

Veterans Administration Medical Center, San Francisco
4150 Clement Street, Room 111 W
San Francisco, CA 94121
(415) 750-6960

ViRx, Inc.
1375 Sutter St., Suite 407
San Francisco, CA 94109
(415) 353-5623

ViRx, Inc.-Palm Springs
1401 N. Palm Canyon Drive, Suite 202
Palm Springs, CA 92262
(760) 864-6266

Community Consortium Sites and Providers

The Community Consortium conducts clinical trials at over a dozen sites in the San Francisco Bay Area. Health care providers who are participating in the Consortium's clinical trials program are listed below. If you are interested in enrolling in a Consortium clinical trial and your health care provideris listed here, you çan discuss enrollment during your next office visit.

San Francisco — Private Practices
Jon Kaiser, MD
Martin Mass, MD
Kenneth Mills, MD
William Owen, MD
Carl Stein, PA

Castro-Mission Health Center - San Francisco
Nilda Alverio, MD
Jane Bailowitz, MD
Deborah Brown, MD
Toby Dyner, MD
Walter Krampf, MD
Lawrence Price, MD
Fred Strauss, MD

Kaiser Permanente AIDS Research Unit — San Francisco
Eric Dummel, MD
Jeffrey Fessel, MD
George Matula, MD

Mission Neighborhood Health Center — San Francisco
Colleen Foy, MD
Ricardo Alvarez, MD
Steve Leiner, NP
Richard Dolbec, MD

San Francisco General Hospital AIDS Outpatient Clinic (Ward 86)
Donald Abrams, MD
Gary Carr, NP
Molly Cooke, MD
Steven Deeks, MD
Stephen Follansbee, MD
Sandra Hernandez, MD
Mark Jacobson, MD
Dennis James, PA
James Kahn, MD
Jill Legg, MD
Catherine Lyons, NP
J. B. Molaghan, NP

San Francisco General Hospital AIDS Outpatient Clinic (Ward 86), continued
Edward Murphy, MD
Meg Newman, MD
Herminia Palacio, MD
Daniel Wlodarczyk, MD

Veterans Administration Hospital, San Francisco
Harry Lampiris, MD

East Bay — Private Practices
Robert Scott, MD

East Bay AIDS Center (Alta Bates Herrick Medical Center), Berkeley
Claire Borkert, MD
Carol Brosgart, MD
Steve O'Brien, MD
Michael D'Arata, FNP
Susan Shea, FNP

Highland General Hospital Adult Immunology Clinic, Oakland
Kathleen Clanon, MD
Howard Edelstein, MD
Jeff Frank, MD
Deborah Royal, NP
Beth Schweitzer, MD
Lisha Wilson, MD

North Bay — Private Practice
Milton Estes, MD
Grace Dammann, MD
Debbie Jernberg, FNP

Access Project

1-800-734-7104
e-mail: AIDSTreatD@AOL.com
Internet: http://health.nyam.org:8000/public_html.network.index.html
A national clearinghouse for information about treatment access. For information about what drugs and treatments are available through federal, state or pharmaceutical-industry-sponsored programs, including:

- Medicaid and AIDS Drug Assistance Programs
- Patient Assistance /Expanded Access Programs
- Information about particular treatments.

AIDS/HIV Treatment Directory

Published twice a year by the American Foundation for AIDS Research, this directory is the most comprehensive source of information on approved and experimental treatments for HIV infections and other HIV-related disorders. Provides current information on clinical trial results, open protocols and enrollment, expanded access/ treatment IND programs, financial assistance programs, and additional resources for HIV/AIDS treatment. For subcription, contact AmFAR.
Phone: (800) 38-AmFAR
Address: 793 Third Avenue, 12th Floor
New York, NY 10017-3204
Email: txdir@amfar.org

AIDS Treatment News

Newsletter reporting on treatments for HIV / AIDS and public policy issues. Published twice a month. Subscription fee (available free or at low cost for people with limited income). Call for information. Highly respected.
Phone: (800) TREAT-1-2
(415) 255-0588
Address: P.O. Box 411256, San Francisco, CA 94141

AIDS Clinical Trials Information Service

Free national hotline, in English and Spanish, for information about AIDS Clinical Trials. Hours are Monday through Friday, 6:00am - 4:00pm (California time).
Phone: 1-800-874-2572 (1-800-TRIALS-A)

Gay Men's Health Crisis Treatment Issues

Reputable newsletter of experimental AIDS therapies published by Gay Men's Health Crisis in New York. Subscription charge.
GMHC Medical Information
129 West 20th Street
New York, NY 10011
FAX: 212-337-3656
Internet: http://www.gmhc.org

Medical Alert

Newsletter of the National Association of People with AIDS
1413 K Street, NW
Washington, DC 20005

National HIV/AIDS Treatment Hotline

1-800-448-0440
For federally approved treatment guidelines and information. Calls accepted from people with HIV, families, friends, health care providers. All calls are confidential.

Project Inform

Sponsors town meetings for information about and discussion of treatment twice a month. Information sheets and newsletter about available experimental drugs in treating AIDS, ARC, and HIV infection. Researches and disseminates information about where and how to obtain experimental drugs, current pricing, and what is known about dosage and clinical trials. California Hot-line. Free, donations for information sheets and newsletters accepted. Knowledgeable staff.
Phone: (800) 334-7422 (California only)
(415) 558-9051
Address: 1965 Market Street, San Francisco, CA 94103
Internet: http://www.projinf.org

Trials Search

A free computerized clinical trials matching service that provides people with HIV with personalized lists of studies for which they may qualify based on their medical history. Database covers all open trials in California. To receive a report, complete the Trials Search questionnaire (found in this Guide or by calling the number below), or conduct your own search at the Trials Search site on the World Wide Web. Trials Search is a service provided by the Community Consortium.

Phone: (800) 492-5777
(415) 476-5777
Address: 3180 18th Street, #201, SF, CA 94110
Internet: http://hivinsite.ucsf.edu/tsearch

WORLD

(Women Organized to Respond to Life-Threatening Diseases)

Newsletter contains updates about clinical trials and treatment information of interest to women. Organization sponsors "HIV-University" (HIV-U) to teach women infected with HIV about all aspects of HIV disease.

Phone: (510) 658-6930
Address: 3948 Webster Street, Oakland, CA 94609

AIDS/HIV Treatment Information Resources on the World Wide Web

HIV InSite	http://hivinsite.ucsf.edu
The Body	http://www.thebody.com
Critical Path	http://www.critpath.org/
AEGIS	http://www.aegis.com/
AIDS Treatment News:	http://www.immunet.org/atn/
Intl. Assoc. of Physicians in AIDS Care:	http://www.iapac.org/
GMHC:	http://www.gmhc.org/
BETA:	http://www.sfaf.org/beta.html
Johns Hopkins	http://www.hopkins-aids.edu
Project Inform	http://www.projinf.org/
AIDS Treatment Data Network:	http://www.aidsnyc.org/network/index.html
Journal of the AMA (JAMA)	http://www.amaassn.org/special/hiv/
Harvard AIDS Institute Link Page	http://www.hsph.harvard.edu/

Northern California Treatment Education and Advocacy Resources

ACT-UP Golden Gate Chapter / Treatment Issues Committee
Political action group. Committee works to reform treatment and drug development priorities and revolutionize the health care delivery system. Many members are very HIV knowledgeable.
Phone: (415) 252-9200 Information & announcements
(415) 252-9275 Office
Address: 519 Castro Street SF, CA 94114

Asian Pacific Islander Wellness Center
Case management and treatment advocate programs help clients learn about and gain access to health care and treatment options on an individual or group basis. Services targeted to Asian-American and Pacific Islander communities. English, Cantonese, Vietnamese, Mandarin, Tagalog and Khmer spoken.
Phone: (415) 292-3400
Address: 730 Polk Street, 4th Floor, SF, CA 94109

Bay Area Perinatal AIDS Center (BAPAC)
Center at San Francisco General Hospital that studies transmission of AIDS from pregnant women to their unborn children. Good source of information about women with HIV/AIDS and pregnancy.
Phone: (415) 206-8919
Address: 1001 Potrero Ave., Room 6D4, SF, CA 94110

New Village
Case management and treatment advocate programs help clients learn about and gain access to health care and treatment options on an individual or group basis. Services targeted to African-American gay, bisexual and transgender communities.
Phone: (415) 356-8140
Address: 973 Market Street, #650 SF, CA 94103

Filipino Task Force on AIDS
Case management, client services, treatment advocacy, information, communication, and education on HIV/AIDS. Services targeted to the Filipino community. Tagalog/English speaking staff.
Phone: (415) 703-9880
Address: 1540 Market Street, #325, SF, CA 94102

Healing Alternatives Foundation
"Buyers Club" for products aimed at improving the health of HIV positive people and people with AIDS, including vitamins, minerals, herbals, nutritional supplements, experimental substances, foreign products and more. Good resource and information library to encourage client participation in their health care program. Library is free, Buyers Club costs $1.00 to join. Open 12:00 to 6:00 pm, Tuesday through Friday; 12:00 to 5:00pm Saturday.
Phone: (415) 626-2316
Address: 1748 Market Street #205, SF, CA 94102

Mission Neighborhood Health Center, La Clínica Esperanza
General medical care, clinical trials and social services for the Latino/a community. Bilingual (Spanish / English) staff.
Phone: (415) 431-3212
Address: 240 Shotwell Street, SF, CA 94110

Native American AIDS Project
Case management and treatment advocate programs help clients learn about and gain access to health care and treatment options on an individual or group basis. Services targeted to American Indian community.
Phone: (415) 522-2460
Address: 1540 Market Street, #425, SF, CA 94102

Options Project, UCSF AIDS Program
Identifies individuals with primary HIV infection and provides those individuals with clinical care. Develops effective treatment programs for HIV infections of less then seven months duration and to see if current treatment plans are capable of eradicating HIV infection when given early in the course of disease. Provides ways of referring high risk individuals into behavioral intervention programs in order to prevent infection.
Phone: (415) 476-9296 ext. 119
Address: SFGH Bldg. 80, Ward 84, SF, CA 94110

Proyecto ContraSIDA por Vida
Case management and treatment advocate programs help clients learn about and gain access to health care and treatment options on an individual or group basis. Services targeted to Latino communities, especially gay, lesbian, bisexual and transgender HIV positive people. Spanish and English spoken.
Phone: (415) 575-1642
Address: 2973 16th St., SF, CA 94110

San Francisco AIDS Foundation
Information and referrals to AIDS service organizations for people who need emotional or practical support. Spanish and Tagalog speaking staff. Publishes **BETA, the Bulletin of Experimental Treatments for AIDS**. **BETA** is published four times a year and has very up to date information on various aspects of HIV infection.
Phone: 1-800-FOR-AIDS (English, Spanish, Filipino)
(415) 863-2437 (**BETA** subscription info.)

Los Angeles Area Treatment Education and Advocacy Resources

AIDS Project Long Beach
2017 E. 4th St.
Long Beach, CA 90814
(310) 434-4455

AIDS Project Los Angeles
1313 N. Vine St.
Los Angeles, CA 90028
(213) 993-1459
(213) 993-1483 (Spanish)
Publishes *HIV LA*, an extensive directory of HIV resources in LA and *Positive Living*, a monthly newsletter that includes timely treatment and clinical trial updates Call for free copies or subscriptions.

AIDS Service Center
126 W. Del Mar Blvd.
Pasadena, CA 91105
(818) 796-5633

Asian Pacific AIDS Intervention Team
605 W. Olympic Blvd., Suite 610
Los Angeles, CA 90015
(213) 553-1871

AIDS Prevention Team
1219 S. La Brea Ave.
Los Angeles, CA 90019
(213) 964-7820

Bienestar Latino AIDS Project
1169 N. Vermont Ave.
Los Angeles, CA 90029
(213) 660-9680

L. A. Shanti
1616 N. La Brea Ave.
Hollywood, CA 90028
(213) 962-8197

WomensLink
4410 Sepulveda Blvd.
Culver City, CA 90230
(310) 313-5139

Laguna Beach Resources

The Laguna Beach Community Clinic
362 Third St.
Laguna Beach, CA 92651
(714) 494-0761 ext 24

Selected San Diego Area Resources

Being Alive Center for Women and Children
3265 5th Avenue
San Diego, CA 92103
(619) 298-5099
Direct services, advocacy and education

Being Alive-San Diego
4070 Centre St.
San Diego, CA 92103
(619) 294-9988
Newsletter, support groups, counseling, housing

Hemophilia Association
P.O. Box 23099
San Diego, CA 92193
(619) 560-8373

San Diego County Department of Health and Human Services / Office of AIDS Coordination
P.O. Box 85222
Administrative Center, Room 208
San Diego, CA 92186
(619) 515-6699

San Diego Health Alliance, HIV/AIDS Office
234 North Magnolia Avenue
El Cajon, CA 92020
(619) 579-8373

UCSD Medical Center
AIDS Testing and Treatment Center
2760 Fifth Avenue, Suite 30
San Diego, CA 92103
(619) 543-8080

Selected Medical Abbreviations:

< :	less than
> :	greater than
≤ :	less than or equal to
≥ :	greater than or equal to
qd:	daily
tid:	three times a day
bid:	twice a day
PO:	by mouth
SQ:	subcutaneous (injected under the skin)
IV:	intravenous (injected in a vein)
IM:	intramuscular (injected in a muscle)
mg.:	milligrams
ml.:	milliliters
mm.:	millimeters

Acquired Immunodeficiency Syndrome (AIDS): failure of the immune system believed to be caused by infection with the human immunodeficiency virus (HIV). The virus infects the body's cells that are essential to the proper functioning of the immune system.

Adjuvant: any substance that enhances the immune-stimulating properties of an antigen or the pharmacologic effect of a drug

Adverse reaction ("side effect"): toxic reaction to a substance. Common adverse reactions include rash, headaches, nausea, vomiting and drowsiness; and can be as severe as anemia, seizures and liver or kidney failure.

AIDS Dementia Complex (ADC): a degenerative neurological condition, generally attributed to HIV disease, with a wide variety of clinical presentations including loss of coordination, mood swings and loss of inhibitions, and widespread cognitive deficit.

Anaphylactic Shock: a life-threatening allergic reaction characterized by a swelling of body tissues (including the throat) and a sudden decline in blood pressure

Antibacterial: a substance which stops the growth of bacteria.

Antibiotic: a substance which kills or inhibits the growth of disease causing organisms, such as bacteria and fungi. For example, penicillin for some bacteria, amphotericin B or nystatin for some fungi.

Antibody: a protein produced by plasma cells in response to a specific antigen. Antibodies bind to antigens, often resulting in the inactivation of the antigen itself or the organism to which the antigen is attached. *See also* Antigen.

Antifungal: a substance which kills or inhibits the growth of a fungus.

Antigen: a substance, especially a protein, which stimulates production of antibodies.

Antiretroviral: a substance that stops or suppresses the activity of a retrovirus (for example, AZT, ddI, ddC). HIV is a retrovirus. There are now antiretroviral drugs that suppress HIV in different ways, such as protease inhibitors and reverse transcriptase inhibitors.

Antiviral: a substance that stops or suppresses the activity of a virus (for example, acyclovir, ganciclovir, foscarnet).

ARC: (abbreviation) *see* AIDS-Related Complex.

Asymptomatic: infection without symptoms. Someone may have HIV disease without showing any symptoms.

AZT intolerant: someone who has severe side effects from taking AZT and cannot continue taking it.

bDNA assay: *see* HIV RNA

Biopsy: removal of a small amount of tissue from the patient, either surgically or with a small needle, for microscopic examination to determine if disease is present.

Blinding: in research, refers to the process of preventing patients and/or their doctors from knowing whether the patient is taking active drug or placebo. *See also* Double-blind.

Bone marrow: soft tissue in the interior of a bone where blood cells are produced.

Bronchoscopy: examination of the bronchi (lung passages) with the aid of a bronchoscope (a tube inserted into the lungs).

Candida: a white, patchy fungus which often grows in the mouth or esophagus of people with AIDS, causing pain or difficulty in swallowing. Infection with *Candida* is known as "candidiasis" or "thrush."

CD4 cell: *see* T-cell

Central nervous system (CNS): the brain and spinal cord.

Cervical Dysplasia: the development of abnormal tissue on the cervix, the outlet of the uterus, may progress to cancer.

Chemotherapy: the treatment of disease by chemical agents; usually refers to cancer treatment.

Clinical trial: a study which tests experimental medicines in human beings.

CMV: (abbreviation) *see* Cytomegalovirus.

Combination therapy (for AIDS): the use of two or more antiretroviral treatments in combination against HIV.

Community-Based Clinical Trial (CBCT): a clinical trial conducted primarily by primary-care physicians, rather than in academic research facilities

Compassionate use: an FDA program that makes certain experimental drugs available to seriously ill people when no other treatment exists or when the patient cannot tolerate other treatments.

Cryptococcal meningitis: a fungal infection caused by *Cryptococcus neoformans* that affects the three membranes (meninges) surrounding the brain and spinal cord. Symptoms include severe headache, dizziness, nausea, loss of appetite, vision disorders and mental deterioration.

Cryptosporidiosis: an opportunistic infection of the intestines caused by a protozoan parasite (*Cryptosporidium parvum*)

Cytomegalovirus (CMV): a virus that can cause aching, fever, mild sore throat, fatigue and enlarged lymph nodes. In AIDS, severe CMV infections can produce hepatitis, pneumonia, retinitis and colitis, leading in some cases to blindness, chronic diarrhea and death.

Diagnosis: determining the cause and nature of an illness

Disseminated: spread throughout the body.

Dose-ranging: drug trial in which different doses of a given drug are compared in order to determine which dose is the most effective and the least toxic.

Double-blind (double-masked): trial procedure in which neither experimental subjects nor doctors know which subjects are receiving the test drug and which are receiving a placebo or other therapy. This method is believed to promote faster and more objective results, as doctors' and patients' opinions about a test drug's efficacy might otherwise bias test results.

Efficacy: a drug passes efficacy trials if it is effective at the dose tested and against the illness for which it is prescribed.

Encephalitis: inflammation of the brain.

Endoscopy: viewing the inside of a body cavity with a device using flexible fiber optics

Expanded access: (also called "parallel track") a procedure established by the FDA which permits the use of investigational drugs by individual physicians. The purpose of this program is to make the drug available to patients who need it, while collecting at least some limited data on efficacy and toxicity.

Experimental drug: a drug that is being tested for use as a treatment for a specific condition in a specific population.

FDA, Food and Drug Administration: The U.S. government department that approves and regulates drugs and medical devices. Pharmaceutical companies must have FDA approval to sell a new medicine.

Herpes: 1) a group of viruses including herpes simplex I (HSV I), herpes simplex II (HSV II), varicella zoster (also called shingles), Epstein-Barr virus, and cytomegalovirus. 2) a common name for blisters on the mouth or genital regions caused by herpes simplex I and II.

Histoplasmosis: a fungal disease resulting from infection with *Histoplasma capsulatum*

HIV: (abbreviation) *see* Human Immunodeficiency Virus.

HIV positive: having antibodies to the human immunodeficiency virus in the body. Implies infection with HIV.

HIV RNA tests: see "Viral Load"

Human Immunodeficiency Virus: a slow-acting retrovirus which many people believe to be the sole or foremost causative agent of AIDS and ARC.

Immune Thrombocytopenic Purpura (ITP): an autoimmune disease, in which the destruction of platelets (thrombocytes) leads to an increased susceptibility to bruising and bleeding.

Immunomodulator: a drug which alters, suppresses or strengthens the immune system.

IND: (abbreviation) *see* Investigational New Drug.

Induction: the initiation of a particular therapy

Infusion: the process of giving a substance (medication, food supplements, etc.) to a patient by injecting it into the blood stream. This procedure can either be a one-time event or continued over many hours, days or months.

Investigational New Drug (IND): an application submitted to the Food and Drug Administration for permission to test a new drug or an old drug for a new indication in humans

ITP: *see* Immune Thrombocytopenic Purpura.

Kaposi's sarcoma (KS): an abnormal proliferation of small, poorly formed blood vessels which occurs in some people with AIDS. KS lesions may first appear anywhere on the body or in the soft palate of the mouth; they may also remain hidden in the internal organs.

Lesion: a change in tissue caused by disease. A point or localized patch of a skin disease. Other words that mean about the same thing as lesion include "sore" or "spot."

Lumbar puncture (LP): insertion of a needle into the spinal column to remove spinal fluid or to inject anesthesia or medicine.

Lymphadenopathy: swollen, firm and possibly tender lymph glands. Causes may range from a temporary infection (such as the flu) to lymphoma.

Lymphoma: a malignancy (cancer) of lymphocytes, the cells that are responsible for normal immune function.

MAC (also called MAI): (abbreviation) *see Mycobacterium avium-Intracellulare* Complex.

Maintenance therapy: use of a treatment to maintain a desired effect that has already been achieved.

Malabsorption syndrome: decreased intestinal absorption resulting in loss of appetite, muscle pain, weightloss and diarrhea

Malignant: used to describe cells or tumors growing in an uncontrolled fashion, either spreading to other sites through the blood stream or invading nearby, normal tissues. By definition, cancers are always malignant, and the term "malignancy" implies a cancer.

Monoclonal antibodies: custom-made immune system pieces that are used against one specific disease-causing agent

Mycobacterium avium-Intracellulare Complex (MAC): in people with AIDS, an infection which begins in the gut or lungs and is similar to tuberculosis. Later, the infection often spreads to other organs by way of the blood stream.

Neoplasm: tissue that grows more rapidly than normal; a tumor or growth. A neoplasm that does not spread to other tissues is described as benign. A neoplasm that spreads (metastasizes) to other tissues is termed malignant, and is commonly called cancer.

Neurological disorders: disorders of the central nervous system (brain and spinal cord), such as seizures or dementia, or of the peripheral nervous system (nerves) such as a neuropathy.

Neuropathy: the name given to a group of disorders involving nerves, whose symptoms range from a tingling sensation or numbness in the toes or fingers, to paralysis. "Peripheral neuropathy" refers to nerves outside the spinal cord, usually in the feet, legs, hands or arms.

OI: (abbreviation) *see* Opportunistic infection.

Opportunistic infection (OI): illness which would not normally occur in someone whose immune system is functioning properly.

Open label trial: (also called non-masked or non-randomized trial) a drug trial in which both doctors and subjects know what drug a subject is taking (and at what dose).

p24 antibody test: a test that measures the amount of antibodies in the blood against the p24 antigen.

p24 antigen test: a test that detects a protein fragment (p24) from HIV's core in blood and other body fluids. Not an accurate measurement of viral activity.

Pancreatitis: inflammation of the pancreas which can result in severe abdominal pain. Pancreatitis can be a side effect of a drug, but can occur due to including gallstones, viral infection and excessive alcohol intake.

Parenteral: not through the mouth. Intravenous, intramuscular, and intradermal routes of administration of drugs are all parenteral

PCP: (abbreviation) see *Pneumocystis carinii* Pneumonia.

PCR (Polymerase Chain Reaction) Test: A test to measure the amount of RNA or DNA (genetic material) of a virus or other organism in the blood or tissue. PCR tests are used to test HIV viral load.

Pharmacokinetics: the study of how drugs are absorbed, processed and eliminated by the body. This helps in determining the best route of administration, dosage and dosing schedule.

Phase I clinical trials: toxicity and dose-finding clinical studies which evaluate the drug's actions in the body, its safe dosage range, how it is absorbed, distributed, metabolized and excreted from the body. These trials are usually completed within a year and involve a small number of research subjects.

Phase II clinical trials: efficacy studies which often include several hundred human volunteers. They are designed to assess the drug's effectiveness precisely and to detect major adverse reactions (side effects).

Phase III clinical trials: involve up to several thousand participants to confirm earlier findings of effectiveness and to find side effects that occur only rarely or after a long period of treatment. They may last several years.

Phase IV clinical trials: studies designed to evaluate the long-term safety and effectiveness of a drug usually carried out after licensure of the drug. Also known as "Post-Marketing" studies

Placebo: an inactive substance against which test drugs (active or "real" drugs) are compared. In placebo-controlled trials the control group takes a placebo, while the test group takes an experimental drug. Many such studies are double-blinded so that neither the patients nor their doctors know which substance the patients are receiving. Placebos are usually harmless.

Platelets (also called thrombocytes): blood cells which help the normal clotting of blood.

***Pneumocystis carinii* Pneumonia (PCP):** a type of pneumonia caused by a common parasite that grows rapidly in the lungs of people with AIDS. PCP is the leading cause of death in AIDS. Rarely, *Pneumocystis carinii* infections may occur elsewhere in the body.

PO: Oral; taken by mouth as pill or liquid.

Prodrug: a class of drug which works after being converted in the body by metabolic processes

Prophylaxis: treatment intended to prevent people from getting a disease. For example, aerosolized pentamidine and Septra® have been shown to be effective for prophylaxis against PCP.

Protease Inhibitor: an antiretroviral drug that prevents HIV from making copies of itself (replicating) by blocking an enzyme called "protease".

Protocol: detailed plan which states a clinical trial's rationale, goal, hypothesis, the drugs involved, dosage levels, methods of administration and treatment durations, as well as who may participate, their disease and its severity.

Radiation therapy: a treatment for cancer using radiation.

Randomized trial: in a randomized trial, participants are assigned by chance to receive one of the treatments being studied.

Rechallenge: to take a drug again despite previous bad side effects.

Refractory: severe disease that is resistant to treatment.

Regimen: any particular treatment plan specifying which drugs are used, in what dose, according to what schedule, and for how long

Remission: when the symptoms of a condition disappear. "Remission" is not the same as "cure," because a disease can sometimes come back after it has been in remission.

Renal disease: disease of the kidney.

Resistance: reduction in sensitivity to a particular drug.

Retinitis: inflammation of the retina, a part of the eye. In people with AIDS, retinitis is often caused by CMV or HSV infections. If left untreated, it leads in most cases to blindness.

Salvage therapy: treatment for patients who are non-responsive to or cannot tolerate other available treatments for a particular condition.

Shingles: see herpes zoster

Side effects: an unintended effect. Some side effects are unwanted, harmful or poisonous (toxic), and are called "adverse reactions."

Spinal tap: *see* Lumbar puncture.

STD: sexually transmitted disease.

Study: a general term for any of a variety of research activities involving the collection, analysis or interpretation of data.

Symptom: any condition occurring because of a disease. For example, coughing is one symptom of *Pneumocystis* pneumonia, and headaches are a symptom of cryptococcal meningitis.

Systemic: throughout the body. Sometimes applies to medications that are taken orally or parenterally that saturate the entire body

T-cells (CD4 cells): also called T4 cells or T-helper cells. The T4 cell enhances the immune response to an infection through a complex series of interactions with other types of cells.

Thrush: a *Candida* infection of the mouth and throat often found in people with HIV infection.

Toxicity: the degree to which a substance is poisonous. Clinical trials determine how much of a drug can be taken safely without having a toxic effect.

Toxoplasmosis ("toxo"): a disease caused by a parasite, *Toxoplasma gondii*, often involving the brain, eyes, heart, liver and lungs.

Vaccine: a substance that contains all or a portion of a disease-causing organism (usually "killed" by heat or chemicals) given for prevention or treatment of a disease. By stimulating production of antibodies, the vaccine helps to protect against infection by that organism.

Viral Load: the number of viral particles (usually HIV) measured in a sample of blood plasma. Viral load test results are given as number of HIV copies or equivalents (Eq) per milliliter. There are two tests to measure viral load: PCR and bDNA.

Virus: microscopic agent which requires a living cell in order to reproduce. When viruses infect cells they can cause disease, often killing the cells they infect. Important viruses include Human immunodeficiency virus (HIV), Herpes and Cytomegalovirus (CMV).

Wasting Syndrome: progressive, involuntary weight loss associated with advanced HIV infection.

White Blood Cells: part of the immune system that protects the body against foreign substances such as disease-producing microorganisms

Index

1263W94
CMV Infection **43**
141W94
HIV Infection **14, 16, 26, 27**
1592U89
AIDS Dementia Treatment **49, 50**
HIV Infection **15, 20, 29, 31**
HIV Infection in Infants and Children **82**
HIV Infection in Children **84**
HIV Infection in Newborns **81**
3TC
AIDS Drug Assistance Program 93
HIV Infection **11, 14, 15, 17, 19, 24, 25, 30-34**
HIV Infection in Pregnant Women and Infants **80**
HIV Infection in Women **78**
HIV Infectionin Infants and Children **82**
Non-Hodgkin's Lymphoma Treatment **65**
Patient Assistance Program 97
5-Azacytidine
Epstein Barr-Associated Malignancies Treatment **64**
9-aminocamptothecin
KS Treatment **61**
90Y-Lym-1
AIDS-Associated Lymphoma Treatment **65**

A

Abacavir ***See*** **1592U89**
Abbott Laboratories
Patient Assistance Program
Clarithromycin 97
Ritonavir 99
ABCD ***See*** **Amphotericin B Colloidal Dispersion**
Access Project **121**
ACT-UP Golden Gate Chapter **123**
ACTG 223: MAC Treatment
Clarithromycin, Rifabutin, Ethambutol **68**
ACTG 293: Cervical Dysplasia Prevention
Isotretinoin **40**
ACTG 301: AIDS Dementia Complex Treatment
Memantine **50**
ACTG 307: HIV Infection
Hydroxyurea, ddI **21**
ACTG 309: TB Treatment
Rifampin, INH, Ethambutol, Pyrazinamide **69**
ACTG 313: HIV Wasting Treatment
Megace, Testosterone **71**
ACTG 323: Oropharyngeal Candidiasis Treatment
Fluconazole **42**
ACTG 325: HIV Infection
Interleukin-12 **21**
ACTG 328: HIV Infection
Interleukin-2 **23**
ACTG 329: HIV Weight Loss in Women
Nandrolone Decanoate **73**
ACTG 336: Cryptosporidiosis Treatment
Nitazoxanide **52**
ACTG 350: CMV Retinitis Treatment
Cidofovir, Ganciclovir **48**
ACTG 359: HIV Infection
Fortovase, Ritonavir, Delavirdine, DMP-266, Adefovir Dipivoxil **10**
ACTG 360: HIV and CMV Infection
Viral Load **20**
ACTG 362: MAC Prevention
Azithromycin **67**
ACTG 365: Pharmacokinetics
Indinavir, Rifabutin **77**
ACTG 368: HIV Infection
1592U89, Indinavir, DMP-266 **29**
ACTG 370: HIV Infection
Indinavir, 3TC, Delavirdine, AZT, d4T **11**
ACTG 373: HIV Infection
141W94, AZT, 3TC, Indinavir, Nevirapine, d4T **14**
ACTG 946: HIV Infection
rgp160 Vaccine **34**
Acyclovir
AIDS Drug Assistance Program 93
Patient Assistance Program 97
Herpes Simplex Treatment **54**
ADAP ***See*** **AIDS Drug Assistance Program**
Adefovir Dipivoxil
HIV Infection **10, 30, 33**
ADEK
Diarrhea Treatment **51**
Agouron Pharmaceuticals
Patient Assistance Program
Nelfinavir 98
AIDS Community Research Consortium 17, 22, 23, 25, 28, 30, 40, 44-46, 56, **115**
AIDS Dementia Treatment **49, 50**
AIDS Drug Assistance Program **93-95**
AIDS Healthcare Foundation 17, 25, 31, 33, 35, 41, 74, **115**
AIDS Oncology Practice at UCSF / Mt. Zion 56, 59, 61, 65, 66, 67, **115**
AIDS Prevention Team **125**
AIDS Project Los Angeles **125**
AIDS Research Alliance 15, 18, 24, **115**
AIDS Research Center/Dept. of Veteran Affairs 76, **115**
AIDS Treatment News **121**
AIDS-Associated Lymphoma Treatment
90Y-Lym-1 **65**
AIDS-Related Lymphoma Treatment
Chemotherapy **63**
AIDS/HIV Treatment Directory **121**
Albendazole
Compassionate Use Program 91
Alpha Interferon
AIDS Drug Assitance Program 93
Patient Assistance Program 97
KS Treatment **58**
ALRT1057 Oral Capsules
KS Treatment **60**
ALVAC HIV Vaccine
HIV Infection in Infants **82**
Alza Pharmaceuticals
Patient Assistance Program
Testosterone patches 99
AmBisome
Compassionate Use Program 91
Cryptococcal Meningitis Treatment **49**
Histoplasmosis Treatment **54**
AMC001: Epstein Barr-Associated Malignancies Treatment
5-Azacytidine **64**
AMC002: KS Treatment
ALRT1057 Oral Capsules **60**
AMC003: Non-Hodgkin's Lymphoma Treatment
Interleukin-2 **66**
AMC004: KS Treatment
Alpha Interferon, Ritonavir, d4T **58**
AMC005: Non-Hodgkin's Lymphoma Treatment
CHOP, d4T, 3TC, Indinavir **65**
AMC006: KS Treatment
9-aminocamptothecin **61**
Amgen, Inc.
G-CSF Patient Assistance Program 98
Amifostine
KS Treatment **59**
Amphotericin B
AIDS Drug Assistance Program 93
Patient Assistance Program 97
Histoplasmosis Treatment **54**
Oral/Esophageal Candidiasis Treatment **42**

Index

Amphotericin B Colloidal Dispersion
Bacterial Infection Treatment **40**
Oral/Esophageal Candidiasis Treatment **41**
Amphotericin B oral suspension
Patient Assistance Program 97
Amphotericin-B, liposomal ***See*** **AmBisome**
Amplicor Viral Load Testing
Patient Assistance Program 97
Anemia
Marrow Plus **39**
Anogenital neoplasms
Alpha Interferon
Patient Assistance Program 97
Aphthous Ulcer Treatment
Thalidomide 39
Treatment IND 91
Asian Pacific AIDS Intervention Team 125
Asian Pacific Islander Wellness Center
Resources 123
Astra Pharmaceuticals
Foscarnet Patient Assistance Program 98
Atovaquone
AIDS Drug Assitance Program 93
Patient Assistance Program 97
Azithromycin
MAC Prevention **67**
AIDS Drug Assitance Program 93
Compassionate Use Protocol 91
Patient Assistance Program 97
AZT
AIDS Drug Assistance Program 93
HIV Exposure in Premature Infants **81**
HIV Infection **11, 14, 15, 17, 19, 24, 25, 30-34**
HIV Infection in Infants and Children **82**
HIV Infection in Newborns **81**
HIV Infection in Pregnant Women **79**
HIV Infection in Pregnant Women and Infants **80**
HIV Infection in Women in Labor **80**
Patient Assistance Program 97
AZT-related anemia
Erythropoietin
Patient Assistance Program 98
AZT/3TC
HIV Infection **32**

B

Bacterial Infection Prevention in Children and Adloescents 85
Bacterial Infection Treatment 40
Bacterial Infections
Ciprofloxacin
Patient Assistance Program 97
Bay Area Perinatal AIDS Center (BAPAC) 78, 81, 115, 123
BAY Positives
HIV+ youth support, education program 112
Bayer
Patient Assistance Program
Ciprofloxacin 97
Mycelex 98
Beer Medical Group 35, 71, 115
Beer Medical Group - No. Hollywood 115
Being Alive-San Diego 125
Biaxin ***See*** **Clarithromycin**
Bienestar Latino AIDS Project 125

bis-POM PMEA ***See also*** **Adefovir Dipivoxil**
HIV Infection **37**
HIV Infection in Children **83**
Bleomycin sulfate
AIDS Drug Assitance Program 93
BMS-180194 ***See*** **Lobucavir**
Boerhringer-Ingelheim
Nevirapine
Compassionate Use Program 91
Patient Assistance Program 99
Bristol Myers Squibb
Patient Assistance Program
d4T 98
ddI 98
Fungizone 97
Hydroxyurea 98
Megestrol Acetate 98
BTG Pharmaceuticals
Patient Assistance Program
Oxandrolone 99

C

California Clinical Trials Medical Group 30, 33, 115
California Partners Study 76, 115
CD4-IgG2
HIV Infection in Children **84**
CD4-zeta Gene Therapy
HIV Infection **17, 28**
Cedars-Sinai Medical Center 71, 115
Celegen
Thalidomide Treatment IND 91
Center for Special Immunology - Beverly Hills 22, 115
Center for Special Immunology - Irvine 12, 22, 25, 35, 115
Cervical Dysplasia Prevention
Isotretinoin **40**
Cervical Dysplasia Treatment
DFMO **40**
Chemotherapy
AIDS-Related Lymphoma Treatment **63**
Children's Hospital and Health Center
Youth and Clincal Trials 112
Childrens Hospital LA Risk Reduction Program 112
Children's Hospital, Oakland 82,85,86, 88, 115
Chinese Herbs
Diarrhea Treatment **52**
HIV Infection **18**
Chiron bDNA Viral Load Testing
Patient Assistance Program 97
Chiron Vision Patient Assistance Program
Ganciclovir Implant 98
CHOP Chemotherapy
Non-Hodgkin's Lymphoma Treatment **63, 65**
Chronic Hepatitis B Treatment
Lobucavir **53**
CI-1012
HIV Infection **28**
Cidofovir
AIDS Drug Assistance Program 93
Patient Assistance Program 97
CMV Retinitis Treatment **48**
Cidofovir Gel
Molluscum Contagiosum Treatment **68**
Cimetidine
Patient Assistance Program 97
Cinarcid ***See*** **Sparfloxacin**
Clarithromycin
AIDS Drug Assitance Program 93
Patient Assistance Program 97
MAC Treatment **68**
Clindamycin
Patient Assistance Program 97
Clofazimine
AIDS Drug Assitance Program 93
Patient Assistance Program 97
Clotrimazole ***See*** **Mycelex**
CMV Infection
Viral load **20**
1263W94 **43**

CMV Retinitis Treatment
Cidofovir, Ganciclovir **48**
Ganciclovir, G-CSF **48**
GEM 132 **47**
ISIS 2922 **44,45**
ISIS 2922, Ganciclovir **44**
Intraocular Cidofovir **46**
Nelfinavir, Ganciclovir **46**
RS-79070, Ganciclovir **47**
Community Consortium 9,37-39,52,70,**115**
Community Eye Medical - Brian G. Terry, MD 44, 45, 46, **115**
Compassionate Use Program **91**
Compazine
Patient Assistance Program 97
CPCRA 038: Nutrition in HIV Infection
Peptamen, NuBasics, Vitamins **70**
CPCRA 039: HIV Infection
bis-POM PMEA **37**
CPCRA 042: HIV Infection
Nelfinavir, Ritonavir **37**
CPCRA 046: Genotypic Antiretroviral Resistance 9
CPI-1189
Pharmacokinetics **76**
Crixivan *See* **Indinavir**
Cryptococcal Meningitis Treatment
Fluconazole, Liposomal Amphotericin B **49**
Cryptosporidiosis Treatment
Nitazoxanide **52**
Nitazoxanide Compassionate Use Protocol 91
CSF Viral Load
HIV Infection **9**
Cyclophosphamide
AIDS Drug Assistance Program 93
Cyclosporin
HIV Infection **18**
Cytomegalovirus *See* **CMV**
Cytovene *See* **Ganciclovir**

D

d4T
AIDS Drug Assistance Program 93
Patient Assistance Program 98
HIV Infection **11-14, 18-20, 27, 30, 33**
HIV Infection in Women **78**
KS Treatment **58**
Non-Hodgkin's Lymphoma Treatment **65**
Dapsone
AIDS Drug Assitance Program 93
Daraprim *See* **Pyrimethamine**
Daunorubicin, liposomal *See* **DaunoXome**
DaunoXome
Non-Hodgkin's Lymphoma Treatment **64**
AIDS Drug Assistance Program 93
Patient Assistance Program 98
Davies Medical Center HIV Institute 22, 31, 33, 47, **115**
ddC
AIDS Drug Assistance Program 93
HIV Infection, pediatric Program 91
Patient Assistance Program 98
ddI
AIDS Drug Assistance Program 93
Patient Assistance Program 98
HIV Infection **12, 13, 18, 19, 20, 21, 27**
HIV Infection in Pregnant Women **79**
Delavirdine
AIDS Drug Assistance Program 93
Patient Assitance Program 98
HIV Infection **10, 11, 13, 14**
Dementia *see* **AIDS Dementia**
Department of Psychiatry, UCSF / VA 76
Desert Hospital Comprehensive Cancer Center 57, **115**
Dexamethasone
AIDS Drug Assistance Program 93
DFMO
Cervical Dysplasia Treatment **40**
Diarrhea Treatment
Octreotide **51**
Questran, ADEK **51**
Chinese Herbs **52**
Didanosine *See* **ddI**
Diethylhomospermine
Non-Hodgkin's Lymphoma Treatment **67**
Diflucan *See* **Fluconazole**
Division of Gastroenterology at SFGH 52, 53, 75
DMP-266
HIV Infection **10, 16, 24, 29, 32**
DOX-SL
Patient Assistance Program 98
Doxorubicin
AIDS Drug Assitance Program 93
Doxorubicin, liposomal *See* **DOX-SL**
Dronabinol
AIDS Drug Assitance Program 93
Patient Assistance Program 98
Drug Information and Clinical Trial Hotline **121**

E

East Bay AIDS Center 17,20,28,32,34,35,43, **116**
Educational Intervention
HIV Transmission **75**
Epivir *See* **3TC**
EPO *See* **Erythropoietin**
Epstein Barr-Associated Malignancies Treatment
5-Azacytidine **64**
Erythropoetin
AIDS Drug Assitance Program 93
Patient Assistance Program 98
Ethambutol
AIDS Drug Assitance Program 93
Patient Assistance Program 98
MAC Treatment **68**
TB Treatment **69**
Exercise
HIV Infection in Men **24**
HIV Wasting Treatment **70**
Expanded Access **91**

F

Filgrastim *See* **G-CSF**
Filipino Task Force on AIDS **123**
Fluconazole
AIDS Drug Assitance Program 93
Patient Assistance Program 98
Cryptococcal Meningitis Treatment **49**
Oropharyngeal Candidiasis Treatment **42**
Flucytosine
AIDS Drug Assitance Program 93
Fortovase
HIV Infection **10, 35, 36**
Foscarnet
AIDS Drug Assitance Program 93
Patient Assistance Program 98
Foscavir *See* **Foscarnet**
Fujisawa Pharmaceuticals
Compassionate Use Program
AmBisome 91
Fujisawa, USA, Inc.
Patient Assistance Program
Pentamidine 99
Fungizone
Bacterial Infection Treatment **40**

Index

G

G-CSF
AIDS Drug Assitance Program 93
Patient Assistance Program 98
CMV Retinitis Treatment **48**
HIV Infection **33**
Gallium Nitrate
Non-Hodgkin's Lymphoma Treatment **62**
Ganciclovir
AIDS Drug Assitance Program 93
Patient Assistance Program 98
CMV Retinitis Treatment **44, 46, 47, 48**
Ganciclovir (oral)
Patient Assistance Program 98
Ganciclovir implant (Vitrasert)
Patient Assistance Program 98
Ganciclovir prodrug ***See*** **RS-79070**
GEM 132
CMV Retinitis Treatment **47**
Gene Therapy ***See*** **CD4-zeta Gene Therapy**
Genotypic Antiretroviral Resistance Testing (GART)
HIV Infection **9**
Gilead Sciences
Cidofovir Patient Assistance Program 97
Glaxo-Wellcome Co.
Patient Assistance Program
3TC 97
Acyclovir 97
Atovaquone 97
AZT 97
Pyrimethamine 99
TMP/SMX (Septra) 99
GM-CSF
HIV Infection **22**
Growth Hormone ***See*** **Human Growth Hormone and Serostim**

H

Harbor-UCLA Medical Center 15, 20, 21, 23, 27, 46, 50, 68, 69, 71, **116**

Healing Alternatives Foundation **123**
Hemophilia Association **125**
Herbs ***See*** **Chinese Herbs**
Herpes Simplex
Observational study **55**
Herpes Simplex (peri-anal) Treatment
Virend 15%, Acyclovir **54**
High Risk Youth Program **112**
Histoplasmosis Treatment
AmBisome, Amphotericin B **54**
HIV and CMV Infection
Viral Load **20**
HIV Exposure in Premature Infants
AZT **81**
HIV Infection **9 - 38**
HIV Infection and the Central Nervous System
Observational study **76**
HIV Infection in Infants and Children
AZT, 3TC Nevirapine, 1592U89 **82**
HIV Infection in Men
Nandrolone Decanoate, Exercise **24**
HIV Infection in Newborns
1592U89, AZT **81**
HIV Infection in Newly Seroconverted 19
HIV Infection in Pregnant Women
ddI **79**
Indinavir, AZT, 3TC **79**
HIV Infection in Pregnant Women and Infants
Nelfinavir, AZT, 3TC **80**
HIV Infection in Women
Nelfinavir, Invirase, 3TC, d4T **78**
HIV Infection in Women in Labor
AZT **80**
HIV Transmission
Educational Intervention **75**
HIV Viral Load
Observational study **38**
HIV Wasting Syndrome
Observational study **74**
HIV Wasting Treatment
Nandrolone Decanoate **70**
Testosterone, Exercise **70**
Megace, Testosterone **71**
Serostim **72**
Thalidomide **73**
HIV Wasting Treatment in Men
Oxandrolone **71**
HIV Wasting Treatment in Women
Oxandrolone **74**
HIV Weight Loss
Observational study **74**
HIV Weight Loss in Women
Nandrolone Decanoate **73**
HIV-IT
HIV Infection **29**
HIV-Related Upper Gastrointestinal Symptoms
Metoclopramide **53**
HIVCare, Saint Francis Memorial Hospital 16, 30, **116**
HIVID ***See*** **ddC**
HIV-I Immunogen ***See*** **Remune**
Hoechst Marion Roussel Inc.
Patient Assistance Program
Pentoxifylline 99
Hoffmann-LaRoche, Inc.
Patient Assistance Program
Alpha Interferon 97
ddC 98
Invirase 99
TMP/SMX (Bactrim) 99
HPMPC ***See*** **Cidofovir**
Human Growth Hormone ***see also*** **Serostim**
HIV Wasting Treatment 72
Patient Assistance Program 98
Human Herpes Virus 8 Project
Developmental study **75**
Hydroxyurea
HIV Infection **18, 19, 20, 21**
Patient Assistance Program 98

I

IL-12 ***See*** **Interleukin-12**
IL-2 ***See*** **Interleukin-2**
Ilex
MGBG Compassionate Use Program 91
IM-862
KS Treatment **57**
Immunex Corp.
GM-CSF Patient Assistance Program 98
Indinavir
AIDS Drug Assistance Program 93
Patient Assistance Program 97
HIV Infection **11, 14-17, 24-27, 29, 32, 33**
HIV Infection in Pregnant Women **79**
Non-Hodgkin's Lymphoma Treatment **65**
Pharmacokinetics **77**
Informed consent **102**
INH
Pharmacokinetics **76**
TB Treatment **69**
Injection drug users and clinical trials
Information about 113

Interferon, alpha *See* **Alpha Interferon**
Interleukin-2
HIV Infection **23, 28**
HIV Infection in Children **83**
Non-Hodgkin's Lymphoma Treatment **66**
Interleukin 10
HIV Infection **10, 12**
Interleukin-12
HIV Infection **21**
Intraocular Cidofovir
CMV Retinitis Treatment **46**
Invirase
AIDS Drug Assistance Program 93
Patient Assistance Program 99
HIV Infection **26**
HIV Infection in Women **78**
ISIS 2922
CMV Retinitis Treatment **44, 45**
Isoniazid *See* **INH**
Isotretinoin
Cervical Dysplasia Prevention **40**
Itraconazole
AIDS Drug Assitance Program 93
Patient Assistance Program 98
Oral/Esophageal Candidiasis Treatment **41**

J

Janssen Pharmaceutica
Patient Assistance Program
Itraconazole 98
Ketoconazole 98
Jeffrey Goodman Special Care Clinic 116

K

Kaiser Permanente - Los Angeles 20, **116**
Kaiser San Francisco Ophthalmology 47, **116**
Kaiser San Francisco - HIV Research Unit 10, 17, 22, 25, 29, 33-35, 39, 49, 71-73, **116**
Kaiser Teenage Clinic 112
Kaposi's Sarcoma *See* **KS**
Ketoconazole
AIDS Drug Assitance Program 93
Patient Assistance Program 98
Kraus Medical Partners 31, 32, **116**
KS Treatment 55 - 62

L

L. A. Shanti
Resources 125
LAC-USC Medical Center: 5P21 Clinic 121
LAC-USC Medical Center 10, 15, 20, 23-25, 33, 34, 40, 48, 53, 56 - 58, 60, 61, 68, 69, 72, 73, 78, 79, **116**
LAC-USC Medical Center - Maternal Child Program 40, 78, 80-89, **116**
LAC-USC Medical Center - Norris Cancer Hospital 62 - 66, **116**
Lamivudine *See* **3TC**
Larkin Street Medical Clinic 112
Leucovorin
AIDS Drug Assitance Program 93
Leukine *See* **GM-CSF**
Leukocyte Interleukin
HIV Infection **23**
LGD1069 *See* **Targretin**
Liarozole
KS Treatment **56**
Liposomal Amphotericin B *See* **AmBisome**
Liposomal Daunorubicin *See* **DaunoXome**
Liposome Co.
Patient Assistance Program
Amphotericin B Lipid Complex 97
Lobucavir
Chronic Hepatitis B Treatment **53**
HIV Infection **26**
Lu 02-584 *See* **CPI-1189**
Lymphoma, Non-Hodgkin's *see* **Non-Hodgkin's Lymphoma**
Lyon-Martin Women's Health Services 74, **116**

M

MAC Prevention
Azithromycin **67**
MAC Treatment 68
Clarithromycin, Ethambutol, Rifabutin **68**
MAI *See* **MAC**
Marcus Conant, MD Clinical Research 54, 57, **116**
Marin County Specialty Clinic 30, 33, 34, 35, 71, 75, **116**
Marinol *See* **Dronabinol**
Marrow Plus
Anemia **39**
Medical Alert 121
Megace
AIDS Drug Assistance Program 93
Patient Assistance Program 98
HIV Wasting Treatment **71**
Memantine
AIDS Dementia Treatment **50**
Mepron *See* **Atovaquone**
Merck Pharmaceuticals
Indinavir Patient Assistance Program 97
Methotrexate
AIDS Drug Assistance Program 93
Metoclopramide
HIV-Related Gastrointestinal Symptoms **53**
MGBG *See* **Mitoguazone**
Microsporidiosis
Albendazole Compassionate Use Program 91
Mission Neighborhood Health Center — San Francisco 123
Mitoguazone
Non-Hodgkin's Lymphoma Treatment **63**
Ilex Compassionate Use program 91
MK-0991
Oral/Esophageal Candidiasis Treatment **42**
Molluscum Contagiosum Treatment
Cidofovir Gel **68**
Mother-Newborn Transmission Prevention
Nevirapine **78**
Myambutol *See* **Ethambutol**
Mycelex
AIDS Drug Assistance Program 93
Patient Assistance Program 98
Mycobacterium avium Complex *See* **MAC**
Mycobutin *See* **Rifabutin**

N

Nandrolone Decanoate
HIV Infection in Men **24**
HIV Wasting Treatment **70**
HIV Weight Loss in Women **73**
National HIV/AIDS Treatment Hotline 121
Native American AIDS Project 123
Nebupent *See* **Pentamidine, aerosolized**
Nelfinavir
AIDS Drug Assistance Program 93
Patient Assistance Program 98
HIV Infection **13, 18, 19, 26, 30, 35-37**
HIV Infection in Pregnant Women and Infants **80**
CMV Retinitis Treatment **46**
KS Treatment **59**
Neupogen *See* **G-CSF**
Nevirapine
AIDS Drug Assistance Program 93
Compassionate Use Program 91
Patient Assistance Program 99

Index

HIV Infection **14, 30**
HIV Infection in Infants and Children **82**
Mother-Newborn Transmission Prevention **78**
HIV Infection 91
New Village **123**
NeXtar Pharmaceuticals
DaunoXome Patient Assistance Program 98
Nitazoxanide
Compassionate Use Protocol 91
Cryptosporidiosis Treatment **52**
Nizoral ***See*** **Ketoconazole**
Non-Hodgkin's Lymphoma Treatment
Gallium Nitrate **62**
Mitoguazone, CHOP **63**
PEG L-Asparaginase **63**
DaunoXome **64**
CHOP, d4T, 3TC, Indinavir **65**
Interleukin-2 **66**
Topotecan **66**
Diethylhomospermine **67**
Norvir ***See*** **Ritonavir**
Novartis Pharmaceuticals
Clofazimine Patients Assistance Program 97
Octreotide Patient Assistance Program 99
NTZ ***See*** **Nitazoxanide**
NuBasics
Nutrition in HIV Infection **70**
Nutrition in HIV Infection
Peptamen, NuBasics, Vitamins **70**
Nutrition in Women with HIV
Observational study **75**
Nystatin
AIDS Drug Assistance Program 93

O

Observational
Herpes Simplex **55**
HIV Infection and the Central Nervous System **76**
HIV Viral Load **38**
HIV Wasting Syndrome **74**
HIV Weight Loss **74**
KS Study **62**
Nutrition in Women with HIV **75**
Octreotide
Diarrhea Treatment **51**
Options Project, UCSF AIDS Program 123
Oral/Esophageal Candidiasis Treatment
Itraconazole 41
Amphotericin B Colloidal Dispersion **41**
MK-0991, Amphotericin B **42**
Oropharyngeal Candidiasis Treatment
Fluconazole **42**
SCH 56592 **43**
Ortho Biotech
Erythropoietin Patient Assistance Program 98
Oxandrolone
HIV Wasting Treatment in Men **71**
HIV Wasting Treatment in Women **74**
Patient Assistance Program 99

P

Pacific Oaks Research Group 25, 28, 32, 37, 47, **116**
Paclitaxel. ***See also*** **Taxol**
KS Treatment **56**
Parke-Davis
Paromomycin Patient Assistance 99
Paromomycin
AIDS Drug Assistance Program 93
Patient Assistance Program 99
Patient Assistance Program 97 - 99
Paul Norwood, MD, FACP **116**
Pediatric ACTG 219: HIV Infection in Children
Observational study **88**
Pediatric ACTG 225: Measles Vaccine in Children
Measles Vaccine **87**
Pediatric ACTG 247: Growth and Nutritional Status in Infants
Infant Formula **86**
Pediatric ACTG 249: HIV Infection in Pregnant Women
ddI **79**
Pediatric ACTG 253: Herpes Simplex/ Zoster Infections in Children
Valacyclovir **87**
Pediatric ACTG 254: Bacterial Infection Prevention in Children
Antibiotics **85**
Pediatric ACTG 255: HIV Infection in Pregnant Women
Observational study **89**
Pediatric ACTG 265: Varicella Vaccine in HIV-Infected Children
Varicella Vaccine **88**
Pediatric ACTG 292: Infant Immune Response
Pneumococcal Conjugate Vaccine **85**
Pediatric ACTG 299: HIV Infection in Children
Interleukin-2 **83**
Pediatric ACTG 310: HIV Infection in Children
bis-POM PMEA **83**
Pediatric ACTG 316: Mother-Newborn Transmission Prevention
Nevirapine **78**
Pediatric ACTG 321: HIV Infection in Newborns
1592U89, AZT **81**
Pediatric ACTG 324: HIV Infection in Women in Labor
AZT **80**
Pediatric ACTG 326: HIV Infection in Infants
ALVAC HIV Vaccine **82**
Pediatric ACTG 331: HIV Exposure in Premature Infants
AZT **81**
Pediatric ACTG 351: HIV Infection in Children
CD4-IgG2 **84**
Pediatric ACTG 353: HIV Infection in Pregnant Women and Infants
Nelfinavir, AZT, 3TC **80**
Pediatric ACTG 356: HIV Infection in Infants and Children
AZT, 3TC, Nevirapine, 1592U89 **82**
Pediatric ACTG 358: HIV Infection in Pregnant Women
Indinavir, AZT, 3TC **79**
PEG L-Asparaginase
Non-Hodgkin's Lymphoma Treatment **63**
Pentamidine
Patient Assistance Program 99
AIDS Drug Assistance Program 93
Pentoxifylline
Patient Assistance Program 99
Peptamen
Nutrition in HIV Infection **70**
Pfizer Inc.
Azithromycin Compassionate Use Program 91
Patient Assistance Programs
Azithromycin 97
Fluconazole 98
Streptomycin 99

Pharmacia Upjohn
Patient Assistance Programs
Delavirdine 98
Rifabutin 99
Pharmacokinetics
CPI-1189 **76**
INH **76**
SCH 56592 **77**
Indinavir, Rifabutin **77**
Piritrexim
KS Treatment **58, 60**
Placebos
Common Questions 101
PMPA
HIV Infection **11**
Prednisone
AIDS Drug Assistance Program 93
Procrit *See* **Erythropoietin**
Project AHEAD **112**
Project Inform **121**
Proyecto ContraSIDA por Vida **124**
Prurigo Nodularis
Thalidomide **68**
Pyrazinamide
TB Treatment **69**
Pyrimethamine
AIDS Drug Assistance Program 93
Patient Assistance Program 99

Q

Quan Yin Healing Arts Center 39, 52, **116**
Quest Clinical Research, San Francisco 44, 46, 47, 48, **116**
Questran
Diarrhea Treatment **51**

R

Radiation
KS Treatment **57**
Reglan see Metoclopramide
Remune
HIV Infection **25**
Rescriptor *See* **Delavirdine**
Retina-Vitreous Group - David Boyer, MD 44, 45, 46, **117**
Retrovir *See* **AZT**
rhIL-12 *See* **Interleukin-12**
rhIL-2 *See* **Interleukin-2**
Rhone-Poulenc Rorer
Sparfloxacin Compassionate Use 91
Spiramycin Compassionate Use 91
Rifabutin
AIDS Drug Assistance Program 93
Patient Assistance Program 99
MAC Treatment **68**
Pharmacokinetics **77**
Rifampin
TB Treatment **69**
Rifapentine
TB Treatment **69**
Rights and Responsibilities of Research Participan **102**
rIL-2 *See* **Interleukin-2**
Ritonavir
AIDS Drug Assistance Program 93
Patient Assistance Program 99
HIV Infection **10, 36, 37**
KS Treatment **58**
Roche Diagnostics
Viral load Patient Assistance 97
Roche BioScience
Oral Ganciclovir Patient Assistance Program 98
Roche-Syntex Laboratories
Ganciclovir Patient Assistance 98
Roferon-A *See* **Alpha Interferon-2A**
Roxane Laboratories
Dronabinol Patient Assistance Program 98
RS-79070
CMV Retinitis Treatment **47**

S

S-1153
HIV Infection **15**
San Diego County Department of Health and Human Services **125**
San Diego Health Alliance **125**
San Francisco AIDS Foundation **124**
San Francisco General Hospital GI Clinic 51, **117**
San Francisco VA Medical Center 55, 69, 71, 74, **118**
Sandostatin *See* **Octreotide Acetate**
Santa Clara Valley Medical Center **117**
Saquinavir *See* **Invirase**
SCH 52000 *See also* **Interleukin 10**
HIV Infection **10, 12**
SCH 56592
Oropharyngeal Candidiasis Treatment **43**
Pharmacokinetics **77**
Septra *See also* **TMP / SMX**
Patient Assistance Program 99
SEQUUS Pharmaceuticals
DOXIL Patient Assistance Program 98
Serono Laboratories
Human Growth Hormone
Patient Assistance Program 98
Serostim *See* **also Human Growth Hormone**
HIV Wasting Treatment **72**
Patient Assistance Program 98
SFGH Department of Neurology 9,50,51
SFGH Dermatology 69
Shared Medical Research Foundation 12, 21, 27, 34, 35, **117**
SmithKline Beecham
Albendazole Compassionate Use Program 91
Patient Assistance Programs
Cimetidine 97
Compazine 97
Sparfloxacin
TB Treatment, Multidrug resistant
Compassionate Use Protocol 91
Spiramycin
Chronic cryptosporidium-related diarrhea
Compassionate Use Protocol 91
Sporanox *See* **Itraconazole**
St. Luke Medical Group & Clinical Trials 25, 35, **117**
Stanford University Medical Center 21, 22, 23, 29, 35, 36, **117**
Stavudine *See* **d4T**
Streptomycin
Patient Assistance Program 99
StressManagement
HIV Infection **38**
Sulfadiazine
AIDS Drug Assistance Program 94
Summit Medical Center Adult 54, **117**

T

Tagamet *See* **Cimetidine**
Targretin
KS Treatment **56**
Taxol *See also* **Paclitaxel**
KS Treatment **59**
TB Treatment
Rifapentine, Isoniazid, Rifampin 69
Rifampin, INH, Ethambutol, Pyrazinamide 69
TB Treatment, Multidrug resistant
Sparfloxacin
Compassionate Use Protocol 91

Index

Testosterone
HIV Wasting Treatment **70, 71**
Patient Assistance Program 99
Thalidomide
Aphthous Ulcers, wasting syndrome Treatment IND 91
Aphthous Ulcer Treatment **39**
HIV Wasting Treatment **73**
Prurigo Nodularis Treatment **68**
The Laguna Beach Community Clinic 125
Thrush *See* **Oral Candidiasis**
Tin Ethyl Etiopurpurin
KS Treatment **55**
TMP / SMX
AIDS Drug Assistance Program 94
TMP/SMX (Bactrim)
Patient Assistance Program 99
TMP/SMX (Septra)
Patient Assistance Program 99
TNF Receptors
KS Treatment **58**
Topotecan
KS Treatment **55**
Non-Hodgkin's Lymphoma Treatment **66**
Toremifine
KS Treatment **61**
Tower Infectious Diseases 32, 37, 41, 42, **117**
Treatment IND 91
Trental *See* **Pentoxifylline**
Trials Search 122
Trimethoprim 94
AIDS Drug Assistance Program 94
Trimethoprim/Sulfamethoxazole *See* **TMP / SMX**
Trimetrexate
AIDS Drug Assistance Program 94
Patient Assistance Program 99

U

UC Davis Cancer Center 58, 59, 61, 62, 65, 66, **117**
UC Davis Medical Center 13, 14, 26, 32, **117**
UC Irvine Department of Ophthalmology 45, 46, 47, 48
UC Irvine Medical Center 26, **117**
UCLA - Jules Stein Eye Institute 48, **117**
UCLA CARE Center 13, 22, 23, 40, 50, 56, 58, 59, 66, 72, **117**
UCLA Medical Center - Pediatrics 79, 81, 85, 87, 88, 89, **117**
UCSD Medical Center AIDS Testing and Treatment Center 125
UCSD Treatment Center 10, 12, 21, 26, 27, 47, 50, 56, 60, 68, **117**
UCSD Treatment Center - Pediatrics 78, 80, 81, 82, 83, 85, 86, 87, 88, 89, **118**
UCSF / Veterans Administration Dept. of Psychiatry 76, **118**
UCSF AIDS Clinic 50, **118**
UCSF AIDS Program at SFGH/ACTU 10, 20, 22, 23, 29, 40, 42, 50, 53, 68, 72, 73, **118**
UCSF AIDS Program at SFGH/ICTU 11, 16, 19, 20, 25, 28, 43, 44, 45, 49, 54, 56, 61, 65 - 68, **118**
UCSF Center for AIDS Prevention 38, **118**
UCSF Drug Research Unit at SFGH 77, **118**
UCSF Infectious Diseases Research 77, **118**
UCSF Pediatric Immunology Program 82, 83, 84, 85, 88, **118**
UCSF Teen Clinic 112
UCSF/SFGH Dermatology 55, **118**
UCSF/SFGH Endocrinology 70, 75, **118**
Unimed Pharmaceuticals
Nitazoxanide
Compassionate Use Protocol 91
Univax Biologics
WinRho SD Patient Assistance Program 99
Upjohn Co.
Clindamycin Patient Assistance Program 99
US Bioscience
Trimetrexate Patient Assistance Program 99

V

Veterans Administration Hospital, San Francisco *See* **San Francisco VA Medical Center**
Videx *See* **ddI**
Vinblastine
AIDS Drug Assistance Program 94
Vincristine
AIDS Drug Assistance Program 94
VIRACEPT *See* **Nelfinavir**
Viral Load
HIV and CMV Infection **20**
Patient Assistance with 97
VIRAMUNE *See* **Nevirapine**
Virend 15%
Herpes Simplex Treatment **54**
ViRx, Inc 17, 18, 22, 25, 26, 28, 29, 54, **118**
ViRx, Inc. - Palm Springs 13, 23, 25, 29, 54, **118**
Vistide *See* **Cidofovir**
Vitamins
Nutrition in HIV Infection **70**
Vitasert *See* **Ganciclovir implants**

W

Wasting studies See HIV Wasting
WinRho SD
Patient Assistance Program 99
WomensLink 125
Resources 125
WORLD: Women with HIV Organization 122
Wyeth-Ayerst Lederle Labs
Ethambutol Patient Assistance Program 98

X

XQ-9302 *See also* **Chinese Herbs**
HIV Infection **18**

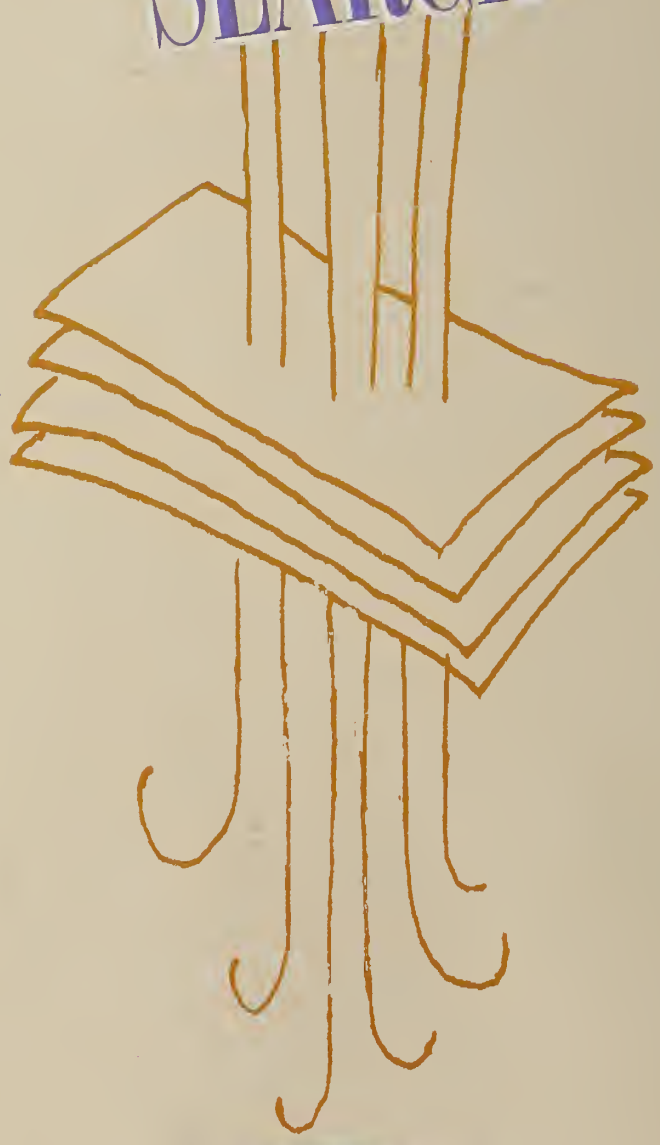
Y

Youth and Clinical Trials 111
Youth HIV Project 112

Z

Zalcitabine *See* **ddC**
ZDV *See* **AZT**
Zerit *See* **d4T**
Zidovudine *See* **AZT**
Zithromax *See* **Azithromycin**
Zovirax *See* **Acyclovir**

TRIALS SEARCH



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